Product Development Collaboration:

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Name: Pulmonary Wellness Formula

Slogan: For intense cough accompanied by spasms of the lungs and upper respiratory tract

Our product is designed with herbs that have been traditionally used to promote bronchial wellness

This product should only be used for short periods of time, do not exceed recommended dosage, do not use during pregnancy or lactation, these statements have not been evaluated by the FDA, this product is not intended to prevent or cure any disease

Part 1: Anatomy and Physiology of respiration.

From a gross perspective, respiration takes place primarily in the lungs. This process can be further subdivided into two primary mechanisms external respiration and external respiration.

The functional anatomy and primary organs involved in the respiratory process include the nasal cavity, the nostril, the oral cavity, the pharynx, the larynx, the trachea, the left and right bronchus, the left and right lungs, the respiratory membrane and the diaphragm.

Tissues involved with respiration includes epithelial tissue, thyroid and haline cartilage, cillia, trachealis muscle, and pulmonary pleura. Within the lungs, the respiratory zone comprises the respiratory bronchioles, alveolar ducts and alveolar sacs. A layer of squamous epithelial cells lines the alveoli and is suffused with a dense web of capillaries which forms the respiratory membrane or “air-blood barrier”

The principal aim of respiration is to supply the body with oxygen and

dispose of CO2. This process occurs in 4 phases: Pulmonary ventilation, External Respiration, Respiratory Transport and Internal respiration.

External respiration is the exchange of gases between the alveoli and the blood, which occurs down the concentration gradient. Oxygen attaches to hemoglobin molecules and is carried through the blood stream. Internal respiration is the opposite of this mechanism where oxygen is absorbed into tissues and CO2 diffuses out of the tissues for transport through the circulatory system to the lungs for expulsion.

This process is deeply intertwined with almost all other physiologic processes. Some especially relevant examples include the somatic and automonic nervous systems regulating the rate of respiration via medullary and pons centers in the brain via phrenic and intercostal nerves; the musculoskeltal system facilitating pulmonary ventilation; the circulatory system plays a central role in gas transport. The endocrine system can module respiratory tissue with hormones such as epinephrine and testosterone.
Emotional input and stress can affect the rate of respiration as in cases of anxiety. The physical environment contributes significantly by determining the quality of the air a person breathes, some examples being second hand smoke or smog. Nutrition is an important input as well insofar as the nutrients and phytochemicals we eat affect our respiratory tissue. Movement, exercise, and rest are also central wellness inputs in maintaining homeostaic respiratory balance because they help create the conditions for maintaining capacity as well as respiratory healing. The breath is also a central component in many mindfulness practices.

Explore Further:

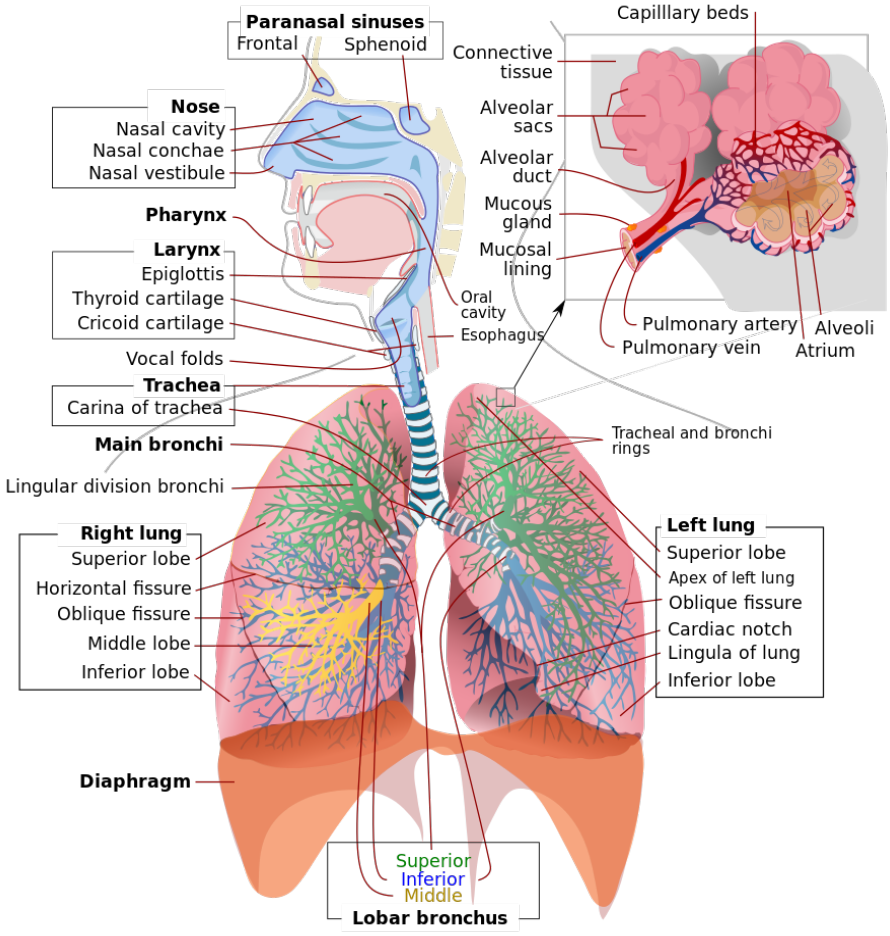

Image Source: (Labeled for reuse)

Videos:

The lungs and pulmonary system | Health & Medicine | Khan Academy

Oxygen movement from alveoli to capillaries | NCLEX-RN | Khan Academy

Part II: Historical Perspectives on Respiration.

Focusing on the processes of respiration from a historical perspective sheds light on traditional herbal use and wisdom. The basic understanding of historical terminology enables a greater understanding of present terminology by promoting a broader understanding of herbal energetics,

actions and applications.

Relevant historical views and contexts:

Galen described the lungs relationship to the body as follows "Blood passing through the lungs absorbed from the inhaled air, the quality of heat, which it then carried into the left heart (“The History of the Lungs,” n.d.). Galenic doctrine ascribed three main purposes to respiration. Respiration cooled the heat of the heart, the pumping action of the chest introduced air into the blood which generated life in the left side of the heart which was distributed through the arteris (sic), and finally the same action served to rid the body of foul vapors (Kinsman, MD, 1927).

Avicenna wrote in his Canon of Medicine: "In the case of the lung, the moisture is not inherent in its nature but is derived from the nourishment which comes to it. The lung is fed by a very 'hot' blood, because there is much bilious humor in the blood going to the lung. A great excess of moisture accumulates in the lung from the gaseous products of the whole body as well as from the materials which flow down to it from the "head” (“The History of the Lungs,” n.d.).

Leonardo da Vinci describes the process of respiration as "From the heart, impurities or 'sooty vapors' are carried back to the lung by way of the pulmonary artery, to be exhaled to the outer air (“The History of the Lungs,” n.d.).

It was not until the experiments of Robert Hooke in the late 1600’s that the understanding that respiration takes place entirely in the lungs and the essential component is a continuous supply of fresh air (Kinsman, MD, 1927).

Around that same period the disciplines of physics, chemistry and physiology intersected to help form the general understanding of respiration that has, with refinements, persisted to this day.

Much work of indexing and systematizing diseases of respiratory passages was conducted by the eclectics. Some examples include but are not limited to:

- Acute Rhinitis a.ka. acute nasal catarrh or acute coryza
- Chronic Rhinitis
- Autumnal catarrh (hay fever)
- Acute catarrhal laryngitis
- Chronic laryngitis
- Spasmodic laryngitis
- Edematous laryngitis
- Acute Bronchitis
- Chronic Broncititis
- FIbrinous Bronchitis
- Bronchiectasis (bronchitis)
- Asthma (Thomas, 1907)

The eclectic school had specific etiology for each disease of the respiratory system. For example: Bronchitis what considered to arise from coexistence of a chronic disease in the bronchial structure with a severe, long continued constitutional diathesis. It follows chronic bronchitis or phthisis more commonly than other conditions. It is immediately induced by violent paroxysms of cough. The real cause of the difficulty is the intense local congestion, caused by the locking up of the secretions of the body.
(Ellingwood, 1910).

In general, from the eclectic perspective, disease may be acute, subacute or chronic, and it is divided, in its various forms of manifestation, into (1) dry, fibrinous or plastic pleurisy, which is the usual form of acute pleurisy. (2) Sero-fibrinous pleurisy—pleurisy with effusion, usually sub-acute in character. (3) Purulent pleurisy or empyema—suppurative pleurisy—and, (4) adhesive pleurisy—pleuritic adhesion—chronic pleuritis. (Ellingwood, 1910)

Diseases of the specifically the lungs included many forms of pulmonary inflammation and pneumonia, their forms are listed:

- Cropous Pneumonia (pneumonia)
- Passive Pulmonary Congestion (lung disease)
- Pulmonary Congestion, Active (lung disease)
- Pulmonary Gangrene

- Pneumonoconiosis
- Hemoptysis (Ellingwood, 1910)

Diseases of the pleura:
- Acute Pleurisy
- Sub-acute Pleurisy
- Empyema
- Adhesive Pleurisy
- Pneumothorax (Ellingwood, 1910)

Definition:—An inflammation of common occurrence, involving the parietal and visceral layers of the pleura.

From historical texts we see that all of the above ailments were considered to be diseases rather than infections, inflammations or virus caused. This was a basis for treatment as disease was considered to be the the underlying issue for ailment. Homeostatic imbalance seemed to be viewed from a different perspective than it is today. In fact, the idea of homeostasis itself was not introduced until the 1920's.

Terms that needed to be looked up:

La grippe - flu
Lassitude - lack of energy, physical or mental weariness
Fetid - foul smelling
Purulency - fluid containing pus
Epistaxis - nose bleed
Lachrymation - flow of tears

Primary Actions:

Trophorestorative / Tonic:

Tonics can be described as herbs that nurture and enliven (Hoffman, 2003). The term trohporestorative is a physiomedicalist term but is

increasingly used interchangeably with the term tonic as both types of actions restore tone and function to a specific tissue (Hechtman, 2013).

The “trophic state” can be seen as representative of the vital capacity of a system or tissue in the body. In chronic states of irritation or depression, some degree of vital deficiency will manifest in the affected tissue, with a gradual loss of functional
capability (Caldecott & Willard, 2010). Caldecott further explains that “In any case where an organ or tissue can be determined to be suffering from a vital deficiency, trophorestoration should be undertaken as a long-term measure to restore normal function”.

Trophorestoatives and Tonics are usually targeted at a specific type of tissue or organ system. In this case we will be examining trophorestoratives / tonics associated with the lungs and mucosal membranes.

Tonifying should be considered a primary action in the interest of a long term return to homeostatic respiratory balance.

Antispasmodic

Antispasmodics ease muscle cramps (Hoffman, 2003). Some antispasmodics alleviate muscular tension throughout the body, whereas some work on specific organs, systems, or types of tissue. Antispasmodics can work on both smooth or skeletal muscle or both (Ganora, 2015).

In this case we will be examining antispasmodics which work on the voluntary and involuntary muscle tissue which is part of / or supports the respiratory system. Antispasmodic interventions should be considered a primary action because effective external respiration is grounded in, and facilitated by muscular action and many of the major dysregulations in the respiratory system have a muscular component.

Anti-tussive

From an allopathic perspective antitussive agents are used mainly to suppress dry, painful and disturbing coughs (Saraswathy, Sathiya, Anbu, & Maheswari, 2014). As a result of this many materia medicas include a list of anti-tussive herbs.

It is important to remember that this is more an example of what an herb is used *for* as opposed to being a true action of the herb or a response of the body to encountering the herb (Ganora, 2015).

Theoretically, anti-tussives are almost all in practice, anti-spasmodics that are specific to the respiratory system.

Anti-catarrhal

Anti-catarrhal herbs eliminate excess mucus, whether in the sinuses or from other parts of the body. Some anti-catarrhals thin the mucous making it easier to expel, others directly prevent mucous secretions. Most of these herbs share astringent actions (Hoffmann, 1988). Their utility in respiratory salutogenesis is obvious.

Expectorant

Expectorants promote the removal of bronchial secretions from the trachea and bronchi (Hoffman, 2003). Expectorants help to expel mucus from the lungs (Tierra, 1990). There are a few types of expectorants: stimulating expectorants, relaxing expectorants and amphoteric expectorants (Hoffman, 2003).

Stimulating Expectorants:

1. Can irritate the bronchioles, which in turn stimulates the removal of materials (Hoffman, 2003).
2. Liquify viscid sputum in order for it to be removed via coughing (Hoffman, 2003). The lesser the viscosity of the material, the easier it is for that material to be cleared.

Relaxing Expectorants:

1. Act via reflux action to soothe bronchial spasms and release mucus secretions (Hoffman, 2003).

2. Promote the production of thinner layers of mucus, which are easier to expel (Hoffman, 2003).

Amphoteric Stimulants:

1. Valuable in many treatments of the lungs and can act as both stimulating or relaxing (Hoffman, 2003).

Bronchiodialator

Bronchiodialator is another modern term describing what an herb is used for. Herbs classified as having this action in modern materia medica are herbs which target specific biological activities such as bronchodilation, mast cell stabilization, anti-anaphylactic, anti-inflammatory, anti-spasmodic, anti-allergic, immunomodulatory and inhibition of mediators (Mali & Dhake, 2011). Many of these herbs in this category are specific indications. There is significant overlap with vasodialators.

Demulcent

Demulcent herbs protect and sooth damaged (Tierra, 1990) irritated and inflamed tissues due largely to their rich carbohydrate mucilage content (Hoffman, 2003). The mucilage is made up of polysaccharide molecules that become slimy when they come in contact with water (Hoffman, 2003). Demulcent herbs indirectly help the lungs by soothing bronchial tension (Hoffman, 2003).

Secondary Actions:

Alterative

Alterative herbs are known as blood purifiers that help move the condition of the body to a more favorable state (Tierra, 1990). Alterative herbs improve the body's metabolic processes to better instate the tissues ability to deal with numerous body functions (Hoffman, 2003).

Diaphoretic

Diaphoretics promote perspiration. This can occur through observable sweating, or normal background perspiration. Diaphoretics often promote dilation of surface capillaries, thus helping to improve poor circulation

(Hoffman, 2003). Relaxant diaphoretics 'open the surface' of tissue whereas stimulant diaphoretics add the qualities of a circulatory stimulant, opening the dermal capillary beds and bringing heat up to the surface. Both types of diaphoretics are constitutionally drying (Ganora, 2005).

Stimulant

Stimulating herbs help increase the body's energy, warm the body, break up obstructions and increase circulation (Tierra, 1990). Stimulants also quicken the physiological activity of the body (Hoffman, 2003).

Vasodialator

Vasodilating herbs dialate blood vessels (Balick, 2014). Many of these herbs intersect with bronchiodialtors and the inclusion of both the tratitional and modern action is to facilitate searching a wider range of materia medica.

Immunostimulant

Immunostimulants nonspecifically stimulate the body's immunological defense system (Hoffman, 2003). Imunostimulats stimulate phagocytes, which fight infection by destroying pathogens (Balick, 2014).

Herbs for Consideration:

Goldenrod

- Herb: *Solidago spp.*
- Parts Used: Leaves, seeds, flowers (Foster & Duke, 2014)
- Preparation: Fluid extract (Grieve, 1971), (Hoffman, 2003)

Goldenrod's actions include anticatarrhal, anti-inflammatory, antimicrobial and diaphoretic (Hoffman, 2003). First nations people used the plant to treat colds and coughs (Foster & Duke, 2014).

Wild Ginger

- Herb: *Asarum Canadense*
- Parts Used: Rhizome and leaves (Foster & Duke, 2014)
- Preparation: Hot infusion (Grieve, 1971)

Wild ginger's actions include diaphoretic, stimulant (Grieve, 1971),

expectorant, tonic and antiseptic (Krochmal, Walters & Doughty, 1969). The plant was traditionally used in chronic chest complaints (Grieve, 1971). First nations people used the plant to promote sweating treat coughs, colds and whooping cough (Foster & Duke, 2014). The plant was also used as snuff to treat congestion of the nose and head (Foster & Duke, 2014). This plant is not on the United Plant Saver “at risk” or “to watch” list, however, due to habitat degradation the plant is not as common as it once was.

Goldenseal

- Herb: *Hydrastis canadensis*
- Parts Used: Root and Rhizome (Foster & Duke, 2014)
- Preparation: Tincture (Hoffman, 2003)

Goldenseal’s actions include alterative, anticatarrhal, anti-inflammatory and antimicrobial (Hoffman, 2003). Goldenseal exerts tonic effects on mucous membranes (Hoffman, 2003). The plant was traditionally used to treat bronchitis and pharyngitis (Foster & Duke, 2014). Goldenseal is on the United Plant Savers “At Risk” list.

Skunk Cabbage

- Herb: *Symplocarpus foetidus*
- Parts Used: Root (Foster & Duke, 2014)
- Preparation: Powder, tincture (Grieve, 1971), decoction or as a powdered root in honey (Hoffman, 2003)

Skunk Cabbage’s actions include antispasmodic, expectorant and diaphoretic (Grieve, 1971). The plant was traditionally used in the treatment of spasmodic cough, whooping cough, asthma (Foster & Duke, 2014), and coughs due to thickened bronchia secretions (Skenderi, 2003).

Self Heal

- Herb: *Prunella vulgaris*
- Parts Used: Whole plant (Foster & Duke, 2014)
- Preparation: Tea (Grieve, 1971)

Self Heal’s actions include antiviral, would healing, antibacterial and tonic (Skenderi, 2003). The plant is used to treat inflammations, wounds, and as an antibacterial agent (Skenderi, 2003).

Coltsfoot

- Herb: *Tussilago farfara*
- Parts Used: Dried flower, leaves (Hoffman, 2003)
- Preparation: Tincture (Hoffman, 2003), tea (Skenderi, 2003)

Coltsfoot's actions include antitussive, expectorant, demulcent, antispasmodic and anticatarrhal (Hoffman, 2003), emollient, antibacterial (Skenderi, 2003). The plant is used to treat inflammations of the upper respiratory tract (Skenderi, 2003). Coltsfoot is used as an expectorant and demulcent for lung congestion, coughs, asthma and bronchitis (Foster & Duke, 2014).

Pipisissewa

- Herb: *Chimaphila umbellate*
- Parts Used: Leaves (Foster & Duke, 2014)
- Preparation: Decoction, fluid extract (Grieve, 1971) or tea (Skenderi, 2003)

Pipisissewa's actions include antibacterial, immunomodulant (Skenderi, 2003), antimicrobial (Foster & Duke, 2014) and alterative (Grieve, 1971). The plant is used in the treatment of the upper respiratory tract (Skenderi, 2003). First nations people used the plant to treat coughs (Foster & Duke, 2014). Pipisissewa is on the United Plant Savers "To Watch" list.

Sundew

- Herb: *Drosera rotundifolia*
- Parts Used: Whole plant (Foster & Duke, 2014)
- Preparation: Tincture (Grieve, 1971)

Sundew has been traditionally used for lung ailments, whooping cough, dry cough, spasmodic cough, bronchitis and asthma (Foster & Duke, 2014). The plant exerts action on all respiratory organs (Grieve, 1971). Sundew is on the United Plant Savers "At Risk" list.

Slippery Elm

- Herb: *Ulmus rubra/fulva*
- Parts Used: Inner bark (Foster & Duke, 2014)
- Preparation: Tea (Grieve, 1971), decoction (Hoffman, 2003), raw or cold water infusion

Slippery Elm's actions include demulcent, emollient, expectorant (Grieve,

1971) and anti-inflammatory (Hoffman, 2003). The mucilaginous plant soothes mucous membrane linings (Hoffman, 2003), penetrates and protects exposed irritated surfaces and relaxes and softens tissues (Strauss, 2014). Slippery Elm was traditionally used to treat pleurisy and coughs (Foster & Duke, 2014). Slippery Elm is on the United Plant Savers "At Risk" list due to Dutch Elm disease, habitat loss and over harvesting.

Buterflyweed/Pleurisy Root

- Herb: *Asclepias tuberosa*
- Parts Used: Root (Foster & Duke, 2014)
- Preparation: Fluid extract, decoction (Grieve, 1971), tincture

Butterflyweed's actions include antispasmodic, expectorant, diaphoretic and tonic (Grieve, 1971). First nations people used the plant for pleurisy, influenza, colds, lung inflammations, asthma, pneumonia and as an expectorant (Foster & Duke, 2014). The plant helps ease breathing and increase expectoration (Grieve, 1971). Butterflyweed is on the United Plant Savers "To Watch" list.

Lobelia

- Herb: *Lobelia inflata L.*
- Parts Used: Dried Aerial Parts (BHMA, 1983)
- Preparation: Dried herb .2 to .6g by infusion or decoction, FE 1:1 50%, FE 1:8 60%

Lobelia is a respiratory stimulant, Antasthmatic, Spasmolytic, Expectorant and Emetic. It is indicated for bronchitic asthma and chronic asthma (BHMA, 1983). There are secondary literature claims that is is toxic in therapeutic doses which are unsubstantiated by primary research (Bergner, 2001). Wild lobelia is considered a USP plant of concern and generally available in commerce.

Grindella

- Herb: *Grindella caporum L.; G. robusta L.;*
- Parts Used: flowerheads before expansion (BHMA, 1983)
- Preparation: Dried flowers 2-3g By Infusion, FE 1:1 22.5%, (BHMA, 1983)

Grindella is Antispasmodic, expectorant and a cardiac depressant. It is

indicated for asthma, bronchitis, upper respiratory catarrh, whooping cough and topically for cystitis and poison-ivy rashes (BHMA, 1983). Many species of grindella are threatened, the herb is cultivated extensively and generally available in commerce (US F&WS, n.d.).

Skullcap

- Herb: *Scutellaria lateriflora L.*
- Parts Used: Aerial parts harvested during the late flowering period (BHMA, 1983)
- Preparation: 1-2g by Infusion, FE 1:1 25%, 1:5 45% (BHMA, 1983)

Skullcap is anticonvulsive and sedative it is used as a tonic and a trophorestorative (BHMA, 1983). It has a generally tonifying and uplifting effect on the nervous system and is a primary supplier of many of the secondary actions identified in the previous section. Skullcap is a common garden cultivar and is generally available in commerce.

Khella

- Herb: *Ammi visnaga L.*
- Parts Used: Fruit (seed) (Skenderi, 2003)
- Preparation: Tincture or tea.

Khella is known for being a smooth muscle relaxant, and a diuretic (Skenderi, 2003). It is particularly effective at reducing spasms of the smooth muscle tissue associated with the respiratory system. It is not listed in the Plants for a future list of threatened plants and is generally available in commerce.

Licorice

- Herb: *Glycyrrhiza glabra L.*
- Parts Used: dried root and stolon (BHMA, 1983)
- Preparation: 1-4g by decoction, FE 1:1 (BHMA, 1983)

Licorice is an expectorant, demulcent, spasmolytic, anti-inflammatory, adrenal tonic and mild laxative (BHMA, 1983). It is indicated for bronchial catarrh, bronchitis as well as many other conditions not specific to the respiratory system (BHMA, 1983). It is widely cultivated and generally available in commerce.

Mullein

- Herb: *Verbascum thapsus L.*
- Parts Used: leaves and stems (BHMA, 1983).
- Preparation: Dried leaves by decoction. FE 1:1 25% (BHMA, 1983)

Mullein is best prepared as a decoction due to the high mucilage content. It is an expectorant, demulcent and mild diuretic (BHMA, 1983). Mullien is indicated in bronchitis, tracheitis, influenzal cold with respiratory catarrh, or any condition with hard coughs and soreness (BHMA, 1983). It is widely cultivated and generally available in commerce.

Schisandra

- Herb: *Schisandra chinensis* (Turcz.) Baill.
- Parts Used: dried fruit (Bone, 1996)
- Preparation: Decoction, FE 1:2 (Bone, 1996)

Schisandra is considered an adaptogen. It is indicated for cough, wheezing and spontaneous wetting (Bone, 1996). It has astringent, antioxidant, hepaprotective, and antitussive properties and is a bronchiodialator. Schisandra is widely cultivated and available in commerce.

Wild Cherry Bark (Prunus)

- Herb: *Prunus serotina Ehrh.*
- Parts Used: bark (BHMA, 1983)
- Preparation: Syrup, Infusion, Tincture and FE 1:1 25% (BHMA, 1983)

Wild cherry bark is antitussive, astringent and mild sedative. It is indicated for persistent coughs or pertussis. It is specifically indicated for cough due to increased irritability of respiratory mucosa (BHMA, 1983). Wild cherry bark is widely distributed throughout NA and generally available in commerce.

Elecampane

- Herb: *Inula Helenium L.*
- Parts Used: Root (BHMA, 1983)
- Preparation: Decoction, FE 1:1 25% (BHMA, 1983)

Elecampane is an expectorant, antitussive, diaphoretic, and bactericidal. It is indicated for bronchial or tracheal catarrh. Cough of pulmonary tuberculosis and irritating cough in children (BHMA, 1983). Elecampane is not endangered and is generally available in commerce.

Yarrow

- Herb: *Achillea millefolium L.*
- Parts Used: aerial parts (BHMA, 1983)
- Preparation: Infusion, FE 1:1 25%, FE 1:5 45% (BHMA, 1983)

Yarrow is a diaphoretic, antipyretic, hypotensive, astringent. It is also a diuretic and urinary antiseptic. It is indicated in the case of fevers and the common cold and performs many of the secondary actions indicated in our search (BHMA, 1983). Yarrow is a common weed in North America and is generally available in commerce.

Horehound

- Herb: *Marribum vulgare L.*
- Parts Used: Leaves and flowering tops (BHMA, 1983)
- Preparation: Infusion, FE 1:1 20% (BHMA, 1983)

Horehound is known as an expectorant and spasmolytic which is in idicated for acute bronchitis or whooping cough (BHMA, 1983). It is especially useful in situations of nonproductive coughing (BHMA, 1983). Horehound is not on the list of threatened or endangered plants and is generally available on commerce.

Storax (sweetgum)

- Herb: *Liquidambar straciflua L.*
- Parts Used: basalm obtained from wood and inner bark (Grieve, 1971)
- Preparation: (Natural Medicines, 2015)

Orally, storax is used for cancer, coughs, colds, diarrhea, epilepsy, sore throats, and parasitic infections. As an inhalant, storax is placed in a vaporizer and used to treat coughs and bronchitis (Natural Medicines, 2015).

Rattlesnake root

- Herb: *Polygala senega L.*
- Parts Used: roots (BHMA, 1983)
- Preparation: Infusion, FE 1:1 60%, FE 1:5 60% (BHMA, 1983)

Rattlesnake fern, also known as rattlesnake root is an excellent

expectorant and diaphoretic as well as being a silagogue and emetic (BHMA, 1983). Rattlesnake root is threatened or endangered in many states in the US.

Bloodroot

- Herb: *Sanguinaria canadensis L.*
- Parts Used: rhizome (BHMA, 1983)
- Preparation: Dried root, FE 1:1 60%, FE 1:5 60% (BHMA, 1983)

Bloodroot is an expectorant, spasmolytic, emetic, cathartic, antiseptic, cardioactive escharotic and topical irritant (BHMA, 1983). It is indicated for bronchitis which is either sub-acute or chronic, asthma, croup, laryngitis and pharyngitis (BHMA, 1983). Bloodroot is on the USP "At risk" list.

Formulation Discussion

We have reached a consensus that we would like to develop an ethanolic extract.

Despite the increased cost associated with extracts, the stability afforded by this extraction method facilitates the product's presence in a wider array of retail storefronts. Furthermore, the longer shelf life affords potential users with the opportunity to have some of the product "on hand when needed" as opposed to only directly appealing to people looking for immediate respiratory support. An ethanolic extract requires no preparation by the consumer and is easy to use anywhere, any time of day. Finally, the constituents of the botanicals we chose share a wide and diverse range of volatility, which complicates blending for powdering or water extractions.

Ethanolic extracts also allow for more granularity in blending and avoid the risk of variance between different servings of a tea. For example it is important to avoid a formulation where there is the potential for one dose

of tea to have an excess of lobelia due to settling in the final product design. Ethanolic extracts also facilitate a more rapid absorption of therapeutic botanicals, which could be a potential asset when focusing on respiratory health.

There is some concern about mucilaginous constituents and tannins, which would be useful in the final product, from being poorly extracted or precipitating out in storage.

There four main areas of inquiry which are being actively pursued this week:

1 - There still some concern about an ethnolic extract being ill equipped to directly interact with the epithelial tissue of the upper respiratory tract, so research is being conducted to determine if the therapeutic benefit of the list of botanicals is effected through direct contact with mucosal linings or stimulation of digestive secretions through activation of taste receptors.

2 - Pharmacodynmaic interactions between the “short list” of botanicals are being researched to ensure that if there are synergistic, additive or antagonistic effects between herbs, these effects are planned for.

3 - Research is being conducted into the solubility of the constituents to ensure that the final blended ethanol concentration is within a range where the formulation is capable of providing a representative “whole plant” extraction for all the botanicals used without causing important constituents to precipitate out due to the polarity of the menstruum.

4 - Research is being conducted to create a list of any interactions, pharmacokinetic or safety indications for the botanicals used.

Formula

"Pulmonis Wellness" Formula

1⁄2 Ml = One Part

Key Herbs: Primary actions, help to direct the action of all other parts

Skunk Cabbage 2 parts 1:3 50%
Elecampane 4 parts (find out)

Supporting Herbs: Have similar actions to the key herbs and help to enhance their action. They also fill in the effects and actions not supplied by the key herbs.

Wild Cherry Bark 2 parts 1:2 50% Skullcap 3 parts 1:2 50%

Balancing Herbs: Help to mask unpleasant flavors, tone down harshness or unnecessary actions and sometimes offer opposite effects to prevent the formula from being too intense.

Rhodiola 2 part 1:3 60% Schisandra 2 part 1:2 50%

Catalysts: Enhance to overall effects of a formula

Licorice 1 part 1:3 35% Lobelia 1 part 1:2 70%

Totaling 8.5 ml
This can be multiplied by 3 = 25.5 ml of product per bottle

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Dosage:

30 ml/1 dropper full 3 times a day
Our product will be marketed in a 30 ml bottle

This product is intended to be used by those suffering from bronchitis, chronic and or spasmodic cough and is not to be used for more than two weeks at a time.

Rationale for Formulation

Energetics & Synergy

Taking energetics into consideration, this formula contains balancing herbs, supporting herbs and catalysts to help guide and even out final tone and action. For example, Skunk Cabbage can be rather harsh so it was important for us to also include Elecampane as key herb as it contains soothing mucilage as well as essential oils which, stimulate expectoration (Hoffman, 2003). Adding supporting herbs such as Skullcap and Wild Cherry bark help to fill action gaps that Skunk Cabbage does not fill. Skullcap is anantispasmodic cooling nervine that also helps tone tissues (Hoffman, 2003). Wild Cherry bark is warming and provides soothing sedative effects (Foster & Duke, 2014). Schisandra is a balancing herb in this formula that offers opposite effects than those of the key herbs. Schisandra is sour and warming (Keys, 1976) while Skunk Cabbage is cooling (Grieve, 1971) and Elecampane is sweet (Tierra, 1990). Rhodiola has been added to increase the overall energy of the formula and decrease stagnation of excess fluid buildup. Catalysts such as, Lobelia and Licorice help to drive and push the formula throughout the body. Licorice also adds a pleasant, uplifting energy and taste to the formula.

Energetics of the Herbs Used:

Skunk Cabbage: Acrid, cool (Grieve, 1971)
Elecampane: Sweet, acrid, bitter, warm (Tierra, 1990) Wild Cherry Bark: Acrid, astringent, warm (Tierra, 1990) Skullcap: Bitter, cool (Tierra, 1990)
Rhodiola: Cool, pungent (Tierra, 1990)
Schisandra: Sour, slightly warming, aromatic (Keys, 1976) Licorice: Sweet, warming (Keys, 1976)

Lobelia: Bitter, neutral (Tierra, 1990)

Phytochemical

Please note that this discussion of constituents is not intended to be a

reductionist justification for choosing plants based on constituents. We hold that whole plant preparations and extracts responsible for the therapeutic benefit of herbal preparations.

Symplocarpus foetidus is a good candiate for tincturing. The raw material contains calcium oxalate raphide crystals (Ganora, 2009) along with essential oil, 5-hydroytryptamine and resins (Hoffman, 2003). These constituents contribute to the irritating and stimulating action of skunk cabbage.

Inula Helenium contains sesquiterpene lactones (primarily helanin), inulun polysaccharides, sterols and resin (Ganora, 2009). These contribute to it's immunostimulating and antitussive effects. The presence of anatol contributes to the warming energetics (British Herbal Medicine Association, 1983).

Prunus serotina contains trace amounts of prunasin a.k.a. benzaldehyde, a cyanogenic glycoside (Ganora, 2009). While this can be broken down by the enzyme system into hydrocyanic acid, *P. serotina* passes the BCP-1973 test of hyrdorcyanic acids (British Herbal Medicine Association, 1983). Wild cherry bark also contains eudsemic acid, p-coumaric acid, scopoletin, sugars and various tannins (Hoffman, 2003) The tannins will be poorly represented in the ethanolic extract. These coumarins are understood to be tonifying to venous and lymphatic systems (Ganora, 2009).

Scutellaria lateriflora contains the flavonoids baicalein, lateriflorin, ikonnikoside, scutellarin (Hoffman, 2003). It also contains phenolic acids and volitale oils as well as the iridoids – ScutelaterinA thru C (Ganora, 2009. Baicalein is extensively studied and these constituents contribute to anti-spasmodic, anti-inflammatory and anti-microbial effects (Ganora, 2009).

Rhodiola rosea contains the flavonoids rhodiolin and rhodionin, tannins, and coumarins. Additionally it contains the monoterpenes rosiridol, the

rosavin glycosides rosavin, rosarin, and rosin. The essential Essential oil contains the fragrant alcohols decanol and geraniol many of these constituents improve the efficiency of the pulmonary circulation and increase the efficiency of the oxygen processing portions of the internal respiratory subsystem (Hoffman, 2003).

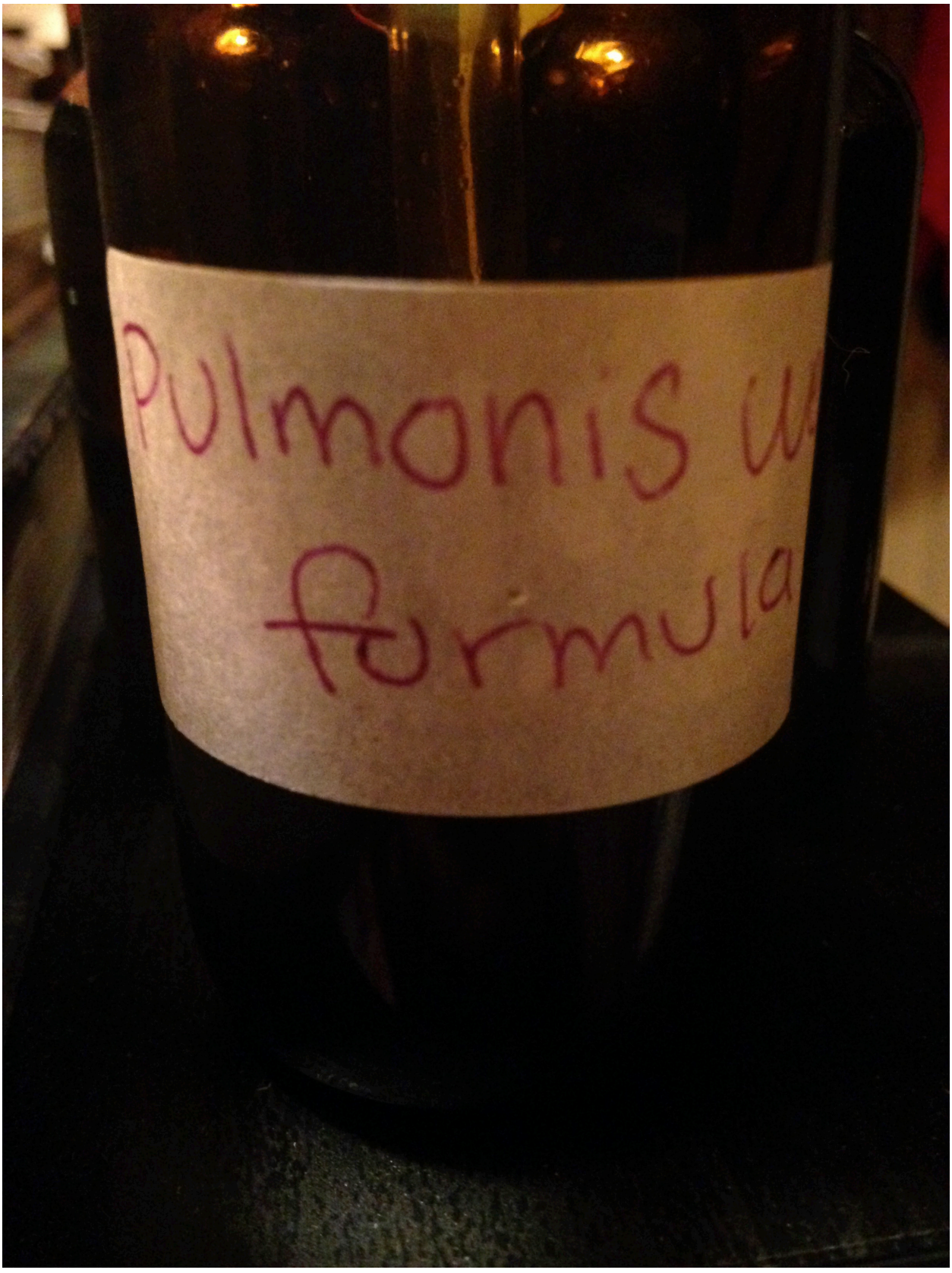
Schisandra chinensis contains lignans in the form of schisandrin, schizabdrols, schisantherins and gomasin A as well as essential oil, resins, pectins, malic, tartaric, nigranoic and citric acid and various tannins (Bowen, 2016). The schisandrins are antioxidant, adaptogenic, hepaprotective, and neuroprotective (Ganora, 2009). The combination of constituents has shown to increase respiratory activity and have expectorant and anti-tussive effects (Bone, 1996).

Glycyrrhiza glabra contains triterpenoid saponins such as glycyrrhizin, glycyrrhetic acid which contribues demulcent and anti-inflammatory effects to the actions of the plant. (Ganora, 2009).

Lobelia inflata contains piperidine alkaloids such as lobeline, lobelanidine, lobelanine and chelidonic acid and resins, gums, and fats. The alkaloids stimulate the respiratory center and produce coughing while also providing a bronchiodialating and smooth muscle relaxant effect (Hoffman, 2003).


50mL
PYREX
echinac
1:1
100 ml
PYREX


MEDICAL
HERBALISM


Pulmonis
formula

Rationale For Each Herb From a Traditional Perspective

Skunk Cabbage was traditionally used in the treatment of spasmodic cough, whooping cough, asthma, (Foster & Duke, 2014) and coughs due to thickened bronchia secretions (Skenderi, 2003). The plant has been used in asthma, whooping-cough, nervous and convulsive affections, hysteria, chronic catarrh, chronic rheumatism, bronchial and pulmonary affections (Sayre, 1917). The roots and seeds are relaxant, diffusive and promote perspiration, and are much valued for antispasmodic coughs, and fevers (Cook, 1869). It is highly valued in hooping-cough, spasmodic asthma, and nervous irritability (Cook, 1869).

Elecampane has been mentioned in ancient texts to support digestion, cause mirth and for the treatment of diseases of women, phthisis, dropsy and in skin affections (Grieve, 1971). The plant was traditionally used for coughs, (Felter & Lloyd, 1898) consumption and other pulmonary complaints such as: bronchitis, asthma and all chronic diseases of the lungs (Grieve, 1971). In folk medicine a tea was made to treat colds, worms, upset stomach and pneumonia (Foster & Duke, 2014). The plant's actions include: Diuretic, tonic, expectorant, alterative, antiseptic, astringent, stimulant, (Grieve, 1971) emmenagogue, and diaphoretic (Felter & Lloyd, 1898).

Wild Cherry Bark was useful during convalescence from pleurisy, pneumonia, acute hepatitis, and other inflammatory and febrile diseases (Felter & Lloyd, 1898). Its chief property is its power of relieving irritation of the mucous surfaces, making it an admirable remedy in pulmonic troubles (Felter & Lloyd, 1898). The plant is well adapted to treat chronic troubles, moderate cough and sustain a patient's strength (Felter & Lloyd, 1898). First nations people used Wild Cherry Bark for fevers, lung inflammations, headache, swollen lymph nodes, sore throats, coughs and laryngitis (Foster & Duke, 2014). The plant was considered an astringent tonic,

pectoral and sedative (Grieve, 1971).

Skullcap is one of the finest nervines ever discovered, and is useful in the treatment of headache arising from incessant coughing and pain according to Grieve (1971). The plant was especially useful for Nervousness caused by chronic diseases, mental or physical exhaustion, teething, nervousness manifesting itself in muscular action, tremors, subsultus, hysteria, with inability to control the voluntary muscles and cardiac disorders (Felter & Lloyd, 1898). The plant was traditionally used as an antispasmodic (Foster & Duke, 2014).

Rhodiola was traditionally used to increase physical endurance, longevity, and productivity, treat exhaustion, infections, depression, nervousness and impotence (Brown, Gerbarg & Ramazanov, 2002). In Asia, a tea of the root was considered the best treatment for cold and flu during the long months of winter (Brown, Gerbarg & Ramazanov, 2002). In his writings, Linnaeus mentioned that Rhodiola was an astringent and useful in the treatment of hernia, leucorrhoea, hysteria, and headache (Brown, Gerbarg & Ramazanov, 2002).

Schisandra has been used in Traditional Chinese Medicine for over 2,000 years to fight fatigue, increase longevity and vitality (Kilham, 2010). Schisandra has been known to calm the spirit, stop diarrhea, generate fluid, stop sweating and retain the essence of lung Qi (Liu, Tseng & Yang, 2004).

Licorice was traditionally used for its action on mucous surfaces, lessening irritation, coughs, catarrh, irritation of the urinary organs, bronchial affections intestinal pain and diarrhea (Felter & Lloyd, 1898). Licorice was valuable in chest complaints and bronchitis (Gieve, 1971). Its actions include: demulcent, pectoral, emollient, (Grieve, 1971) nutritive, (Felter & Lloyd, 1898) and mildly expectorant (Pharmaceutical Society of Great Britain, 1911).

Lobelia was traditionally smoked by first nations people for the treatment of asthma, sore throat, cough and bronchitis (Foster & Duke, 2014). The plant was used in colonial America as a sediitive, for whopping cough, asthma and fevers (Foster & Duke, 2014). Lobelia was also said to

enhance the actions of other herbs (Foster & Duke, 2014). Thompson claimed that Lobelia: removed obstruction, reduced fever, stimulated internal secretions, runs like electricity through the nervous system, caused relaxation in the bronchial spheres and reduced fever (Wood, 1992). Grieve considered the plant excellent in the treatment of bronchitis (1971). Lobelia's actions include: Anti-asthmatic, (Grieve, 1971) nauseant, emetic, expectorant, relaxant, antispasmodic, diaphoretic, sialagogue, sedative, and, secondarily, occasionally cathartic and diuretic and astringent (Felter & Lloyd, 1898).

Rationale For Each Herb From a biomedical Perspective

There is scant modern research on *Symplocarpus foetidus*. We know that it contains high amounts of calcium-oxalates and tannins (Duke, 2016). The combination of these constituents contributes to the unique actions of skunk cabbage. Skunk cabbage tannins precipitate proteins and have antiraduclar properties working to mitigate nerve stimuli "radiated" along the dermatome of a nerve (Uchida et al., 1990). These constituents work to facilitate the reduction of irritation leading to spasmodic cough in the respiratory system.

While it is important to resist a reductionist interpretation of the constituents in *Inula helenium*, elecampane contains alantolactone in a phytochemical mixture known as helenin as well as azulene, and inulin (Duke, 2016). Helenin compounds are anti-inflammatory and antibacterial (Botatto, et. al., 1994). Inulin coats and soothes epithelial tissue (Reiter & Brandt, 1985) while simultaneously serving as an expectorant (Lim et al., 2007).

Prunus serotina contains amygdalin and prunasin these hydrolyze into hydrocyanic acid. (Duke, 2016). These exogenous cyanogenic glycosides are rapidly excreted by lung tissue are where they contribute to *P. serotina's* renown antitussive effect by creating a sedative action on nervous tissue leading to an anti-tussive and bronchiodilating effect

(Bone, 2003) & (Ibarra- Alvarado et al., 2010).

Scutellaria lateriflora contains baicalein lateriflorin, ikonnikoside, scutellarin and Scutelaterins A-C as well as phenolic acid (Pengelly, 2004). It is most likely the synergy of these constituents that leads to skullcaps biomedical effects. These constituents are poorly researched in vitro but appear to bind with GABA-A areceptor sites potentiating the effect of endogenous GABA and creating an inhibitory effect on nerve transmission (Awad et al., 2003).

Rhodiola Rosea contains hundreds of constituents (Pengelly, 2004). Research indicate that these constituents, reduce cortisol, protein kinases, nitric-oxide, and pro-inflammatory proteins (Panossian, Wikman, & Sarris, 2010). These mechanisms contributed the associated adaptogenic, anxiolytic and stimulatory effects.

Schisandra chinensis has been extensively studied. The lignans, schizandrin and gomisinA, have been shown to provide a stimulatory effect to humoral and cell mediated immune responses by inducing interleukin (IL)-8, macrophage inflammatory protein- 1β, and granulocyte-macrophage- colony stimulating factor (GM- CSF) release by THP-1 cells (Bone, 2003). A lignan, schizandrin has shown hepatoprotective, antiviral and neuroprotective in vitro (Bone, 1996). These same constituents have shown to increase respiratory lung debt and rate of breathing. Through these mechanisms schisandra can counteract the effects of dyspena in an unbalanced respiratory system.

Glycyrrhiza glabra contains the triterpeoidsaponis glycyrrhizin (GL), glycyrrhetic acid (GA) and the flavonoids liquiritin, isoliquiritin. In studies, oral doses of GA have an anti-tussive effect similar to codeine (Bone, 2003). GL and GA have both been shown to have topical anti inflammatory effects on epithelial tissue (Bone, 2003) . The flavonoids have also shown to be profoundly antiviral and antimicrobial against a wide spectrum of pathogens (Bone, 2003). Licorice has also been shown to reduce throat irritation and coughing in patients post intubation

(Ruetzler et al., 2013).

Lobelia inflata contains the piperidine alkaloids, including lobeline, lobelanine, and lobelanidine (Duke, 2016). These constituents excite pulmonary afferent nerves, promote expectoration, and can help to free secretions, and can aid respiration (Stanbury et. al., 2013). Lobeline is also reported to inhibit the release of catecholamines from adrenal glands and has also been shown to stimulate the release of prostacyclin from the lungs, suggesting an input in pulmonary vascular inflammation (Stanbury et. al., 2013).

So from a biomedical perspective. Skunk cabbage reduces bronchospasm and performs an astringent effect on the epithelial tissue. Elecampane contributes an antibacterial and anti- inflammatory effect on epithelial tissue as well as stimulating the productive cough reflex. Wild cherry is a bronchodilator and suppresses unproductive coughs. Skullcap binds GABA receptors and inhibits nervous system excitation. Rhodiola reduces cortisol and pro-inflammatory markers. Schisandra increases lung depth and also acts against pro inflammatory cytokines. Licorice is anti-inflammatory, soothing to epethelial tissue, anti-tussive and anti-viral. Lobelia is an expectorant and supports the cough reflex.

Safety Considerations:

Skunk Cabbage

- No side effects or interactions have been reported (Hoffman, 2003)
- Most members of the Araceae plant family are toxic due to cyanogenic glycosides that free hydrocyanic acid (Skenderi, 2003).
- Roots are considered toxic exceot in small doses (Foster & Duke, 2014)
- Small amounts could cause vertigo, vomiting, headache and narcotic effects (Foster & Duke, 2014)
- Skunk Cabbage should only be used by an experienced practitioner (Skenderi, 2003)

- Skunk Cabbage should not be used during pregnancy and lactation (Skenderi, 2003).
- Those with ulcers, kidney stones and cardiovascular problems should not use Skunk Cabbage (Skenderi, 2003).
- May cause skin irritation
- May cause upset stomach

Elecampane

- May cause allergic reaction in those sensitive to plants in the Asteraceae family (Hoffman, 2003)
- Sesquiterpene lactones, particularly alantolactone may cause irritations (Foster & Duke, 2014)
- Elecampane should not be taken during pregnancy and lactation (Skenderi, 2003)
- At higher than normal doses Elecampane may cause gastrointestinal irritations (Skenderi, 2003)
- No reports or side effects when used properly (Skenderi, 2003)

Wild Cherry Bark

- Large doses are toxic (Hoffman, 2003)
- Leaves, bark and seeds contain prunasin, which when digested converts to hydrocyanic acid (Foster & Duke, 2014)
- Bark is most toxic when harvested during the fall (Foster & Duke, 2014)
- Wild Cherry bark should not be taken during pregnancy and lactation (Skenderi, 2003).
- Wild Cherry bark products should be standardized to cyanogenic glycocide content (Skenderi, 2003).

Skullcap

- When used properly, there are no reports of side effects or contraindications (Skenderi, 2003)
- Skullcap may interfere with and or potentiate the effects of sedative prescription medications (Hoffman, 2003).

Rhodiola

- Rhodiola should not be used in cases of nervousness, sleep disorders or hypertension (Skenderi, 2003)
- Unless directed by a health professional, Rhodiola should not be used for more than 10 to 20 days (Skenderi, 2003)

- Rhodiola should not be taken with MAOI anti depressant drugs (Skenderi, 2003)
- Rhodiola can cause vivid dreams and interfere with sleep and should therefore be taken early in the day (Brown, Gerbarg & Ramazanov, 2002).
- Rhodiola is contraindicated in those suffering from bipolar and manic disorder (Brown et al., 2002).
- Rhodiola is generally safe and well tolerated (Braun & Cohen, 2015)
- Side effects are mild (Braun & Cohen, 2015)

Schisandra

- When used properly, there are no reports of side effects or contraindications
- Schisandra should not be used for more than three months (Skenderi, 2003)
- Schisandra should not be used during pregnancy and lactation (Skenderi, 2003)
- Stomach upset has occurred in rare cases (Skenderi, 2003)

Licorice

- Licorice should not be taken during pregnancy and lactation (Skenderi, 2003)
- Not to be used during pregnancy and lactation (Skenderi, 2003)
- Licorice is contraindicated in those with kidney disorders, liver disorders, hypertension and low potassium levels (Skenderi, 2003).
- Licorice should not be taken for more than 4 to 6 weeks due to glycyrrhizin (Skenderi, 2003)
- Excessive use may cause headache, dizziness, weak limbs, hypokalemia, spastic numbness, edema and dizziness (Hoffman, 2003)
- Excessive use may cause high blood pressure (Braun & Cohen, 2015)
- Contraindicated in patients taking cardiac glycosides, diuretic drugs, MAOI drugs, hypotensive agents, cardiac glycosides or corticoids (Hoffman, 2003)

Lobelia

- Lobelia should not be used during pregnancy and lactation (Hoffman, 2003).
- Side effects include: Nausea, vomiting, diarrhea, coughing, tremors

and dizziness (Hofman, 2003)

Product Warning Label:

This product should not be taken during pregnancy and lactation

Consult with a health care practitioner before using this product

This product should not be used for more than 10 days at a time

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