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Combination Homeopathy Products in the Retail Setting

INTRODUCTION

Homeopathic medicines have been used for treatment of illness for more than 200 years. Currently, many economical over-the-counter (OTC) homeopathic formulations exist that are indicated for everyday ailments and minor injuries. Used correctly, OTC homeopathic medicines provide a safe and effective option for patients with common self-limiting illnesses.

The popularity of homeopathic medicines among the public is well established.¹ With recent concerns over adverse reactions associated with conventional pharmaceutical OTC drugs, notably and most recently children's cough and cold products² and formerly decongestant products for adults³, homeopathic medications provide practitioners with viable options for patient recommendations for self-limiting conditions. For these various reasons, it is important that all health care providers be familiar with the basic principles of homeopathy, as well as of the OTC products that consumers are likely to find in drug stores.⁴

WHAT IS HOMEOPATHY?

The National Center for Complemen-

tary and Alternative Medicine defines homeopathy as an alternative medical system, built upon a complete system of theory and practice, that has evolved apart from, and earlier than, the conventional medical approach used in the United States.⁵ As such, homeopathy has a system of pathophysiology, diagnosis and treatment that differs from conventional medicine and drug therapy as practiced by M.D.'s, D.O.'s, NP's and PA's and other conventional allied health professionals in the United States today.

Medicines used in homeopathy are derived from a variety of sources, including botanical, zoological (insect, reptile or animal/human material or byproducts), mineral and pharmaceutical substances. Homeopathic dosage forms can vary considerably; however, they most commonly are manufactured in the form of a tablet and globule, also called a pellet (of varying sizes made of pure sucrose, lactose or other appropriate polysaccharide), and in syrup or other liquid formulations for oral administration. Consumers also can find homeopathic medicines in nasal, otic and ophthalmic solutions and in creams, ointments and gels for topical application. Homeopathic prod-

ucts can be found as a single ingredient or as a combination product of homeopathic medicines indicated for a specific ailment or group of symptoms.

Many homeopathic medicines will have botanical names, similar to herbal products or formulations. The clinician can easily distinguish between a botanical or herbal formulation and a homeopathic medicine by looking at the strength of the ingredient(s). Botanical or herb ingredients will be listed in milligram or gram strengths, while the homeopathic ingredient's strength will be designated by a number followed by X or C potency.

HIGHLIGHTS OF HOMEOPATHY'S DEVELOPMENT

The founder of the system of homeopathy was Samuel Hahnemann (1755-1843), born in Meissen, Saxony, Germany.⁶ His experiments with *Cinchona officinalis*, an herbal medicine used to treat malaria, led to the Hippocratic principle of *similia similibus curantur*, or "likes are cured by likes," which is the basis of the first principle of homeopathy, the Principle of Similars. The term homeopathy is derived from the two Greek words

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Program Goal:

To increase the clinician's understanding of homeopathy and enable him or her to counsel patients regarding over-the-counter products for common illnesses and minor injuries.

Learning Objectives

Upon completion of this program, the clinician practitioner should be able to:

1. Recall the basic concepts and principles used in the application of homeopathic drugs.
2. Identify patients who may benefit from combination homeopathic drug products.
3. Describe the regulations in place in the United States for the manufacture and sale of homeopathic drugs.
4. Appropriately counsel patients on the use of the OTC combination homeopathic drugs.
5. Identify resources for additional information regarding homeopathy.

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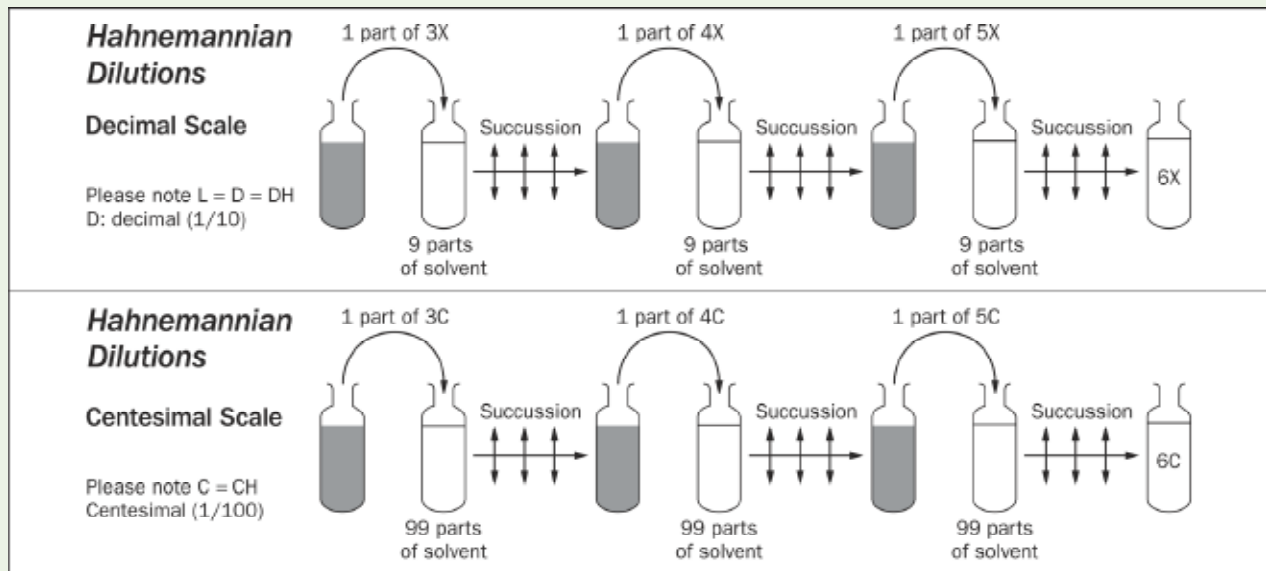
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FIGURE 1

Method for making X and C potencies



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homoios (similar) and *patheia* (suffering).⁷

The homeopathic principle of "minimum dose" or "infinitesimal dose" materialized as a result of Hahnemann's extensive experimentation with many substances and culminated with a methodology for preparing these very dilute therapeutic agents. The process of making different strengths of homeopathic drugs is termed potentization. A process called succussion is used to potentize a substance. Succussion is performed at each step in a series of dilutions where the container holding the mixture is struck forcefully multiple times against a resilient surface (e.g., originally a leather-bound book), producing stronger effects with each dilution increment. The more times the substance is succussed, the stronger its effects and its potency is increased, so a 3 X or C potency is weaker than a 30 X or C potency.

The first combination homeopathic drugs were produced and marketed in the United States in 1854 by Frederick Humphreys, M.D., (1816-1900), a gradu-

ate of the Homoeopathic Medical College of Pennsylvania.⁸ Called Humphreys' Specifics, the drugs were successful in the marketplace and are still sold today.⁹

Currently, there are many successful single and combination homeopathic products available to patients. The combination OTC products are primarily obtained in retail stores, and single agents are more often obtained directly from homeopathy practitioners.

Homeopathic products are widely distributed in most retail channels. These medicines can be found in more than 30,000 outlets nationwide, including drug stores, health food stores, mass merchandise stores and doctors' offices.¹⁰ It is estimated that homeopathic medicines represent from \$600 million to \$800 million across food, drug and mass.¹

BASIC CONCEPTS AND PRINCIPLES OF HOMEOPATHY

Basic principles of homeopathy include the Principle of Similars, the practice of individualizing therapy for each

patient and the use of very small doses of active agent. The Principle of Similars has already been described, as has the principle of minimum or infinitesimal dose. The principle of individualizing therapy is related to these.

Given what Hahnemann proposed—that a substance with the same "picture" or group of attributes as the group of symptoms manifested in the ill patient can be used for the cure of that illness—it follows that individualization of therapy would be an important principle. A single drug can be useful across a variety of body systems and abnormal conditions (or diagnoses), yet this drug must also be specific (have characteristics like the specific expression of the condition in the patient) for it to have a curative effect.¹¹ In classic homeopathic practice, a single homeopathic drug is chosen after a full evaluation of the patient's complete symptom picture, which may include distinct conventional diagnoses, as well as sometimes seemingly unrelated, separate physical, mental and emotional

symptoms going on in the patient.

To be proficient at selecting single-drug therapies, especially for chronic or complex illnesses, a formal education in both medicine and homeopathy is necessary to develop specialized case-taking skills, a working knowledge of hundreds of homeopathic drugs and experience managing cases using homeopathic medicines.

There are variations to this classical approach. One of these variations is to use a combination of homeopathic medicines simultaneously, in a single dosage form, for the treatment of a specific condition or illness. As with other OTC products, combination homeopathic products are intended primarily for home use by non-professionals, and many people report good results with their use.¹² Combination products combine medicines with different symptomatic indications relevant to the patient's condition and are available to treat several common ailments, including common colds, earache and teething pain. Combination products require no individualization because they contain a number of homeopathic drugs indicated for the particular condition covering a variety of symptom complexes that typically occur in members of the general population who have that condition. This makes it possible for individuals who do not have extensive homeopathic training to select an appropriate product for their need.

REGULATION OF HOMEOPATHIC DRUGS

The Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. § 201 *et seq.*, Section 201(g)(1) of the FD&C Act, 21 U.S.C. § 321(g)(1) regulates homeopathic drugs, defining the term drug as an article recognized in official compendiums or pharmacopoeias of the United States. The official compendium, per Section 201(j) of the act, 21 U.S.C. § 321(j), is the most cur-

rent edition of the Homeopathic Pharmacopoeia of the United States (HPUS), the National Formulary, or the United States Pharmacopeia.¹³ Homeopathic drugs are also regulated under the Federal Trade Commission and the Bureau of Tobacco, Alcohol and Firearms, as are allopathic OTC products.¹³

Eligibility criteria for homeopathic

Combination products combine medicines with different symptomatic indications relevant to the patient's condition and are available to treat several common ailments, including common colds, earache and teething pain.

drugs are defined by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), which comprises physicians, pharmacists, homeopaths, lawyers, biochemists and botanists, ensuring that these criteria are met before a homeopathic drug is added to HPUS revisions or supplements.¹⁴ For a homeopathic agent to be included in the HPUS, each of the following criteria must be met:

- The drug is safe and effective.
- The drug has been prepared according to the specifications of the General Pharmacy and relevant sections of HPUS.
- The submitted documentation must be in an approved format as set forth in the relevant sections of HPUS and must include any data relevant to toxicity.¹⁵

In addition, therapeutic benefit of the

agent must be demonstrated by at least one of the following four criteria:

- A homeopathic drug proving and clinical verification acceptable to the HPCUS (refer to the HPCUS Guideline for Homeopathic Drug Proving and the Guideline for Clinical Verification for more information).

- Published documentation, including the symptom picture and any subjective and/or objective symptoms, that the substance was in use prior to 1962.

- At least two adequately controlled, double-blind clinical studies, using the drug as the single intervention, that demonstrate statistical difference from placebo and provide an adequate description of the symptom picture acceptable to the HPCUS.

- Data gathered from clinical experience encompassing the symptom picture, pre- and post-treatment, including any subjective and/or objective symptoms, or data documented in the medical literature.

The above criteria are accepted in place of the Food and Drug Administration's (FDA) new drug application or OTC drug monograph procedures used for conventional pharmaceutical drug approval.¹⁵

According to Section 502 of the FD&C Act, a homeopathic product must be labeled in accordance with the provisions of the HPUS. Homeopathic drugs are covered by the Medicare-Medicaid Statute, 42 U.S.C. § 1395x(t), which defines drugs to "include only such drugs ... as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary or the United States Homeopathic Pharmacopoeia."

The HPUS contains more than 1,200 monographs that specify each drug's nomenclature; origin; botanical, zoological

or chemical description and classification; requirements for preparation; and medication status (i.e., the lowest potency at which a product can be sold as a prescription or nonprescription oral, topical or pharmaceutical necessity). The great majority of homeopathic drugs are OTC in commonly available potencies.

The FDA's Compliance Policy Guide 7132.15 (also known as 400.400) describes the conditions under which homeopathic drugs may be marketed, including labeling requirements. For homeopathic medications, the strength is not labeled in grams or milligrams, but as a homeopathic potency, and an expiration date is not required on the label.¹⁶ The FDA has allowed the continued use of Latin names for the remedies on the labels because, in some cases, the Latin name is necessary to distinguish between drugs that are derived from a number of different species within a particular genus. The HPUS lists official short names that can be used in place of the longer, Latin names. Because a single individual drug may have many indications, manufacturers are required to list at least one indication (not all of them) on single-drug products. More than 1,200 of approximately 3,000 remedies in historic use or extensive current use have been recognized by the HPCUS, as indicated by the HPUS on their labels, while the remainder lack the necessary verification data or have not yet been submitted for approval.

The requirements for nonprescription labeling of homeopathic medicines include:¹⁷

- An ingredients list with accompanying purpose for each ingredient.
- Instructions for safe use.
- At least one major indication.
- Potency (for example, 6C or 12X).

Other information found on the OTC labels of homeopathic products includes¹⁵:

- The letters HPUS, indicating the drug was made in accordance with FDA standards.
- Conventional pharmaceutical label information, including the manufacturer,

name and address, NDC number, UPC code and lot or control number, declaration of net contents, warnings, tamper-evident statement, storage instructions, and prescription-only statement if the drug and/or potency is designated as such in HPUS.

- Adverse-event reporting telephone number.

Exceptions to conventional pharmaceutical and herbal label information include¹⁵:

- An FDA waiver of the requirement for an expiration date because measuring most homeopathic drug products for deterioration of contents using current technology is beyond the point of detection. However, many homeopathic manufacturers provide an expiration date on their product packages even though it is not required.

- Homeopathic drugs are not required to display a supplement facts box or a disclaimer statement as is the case for herbs and supplements that are regulated under the Dietary Supplement Health and Education Act of 1994.

In 1999, the FDA finalized regulations that standardized OTC drug label requirements. May 2002 was the effective date for most OTC medicines to imple-

ment the new labeling requirements, although manufacturers were allowed to distribute existing stocks with older labels. The new requirements establish a standardized Drug Facts label, which presents information regarding active ingredients, purpose, uses, warnings, dosage instructions and inactive ingredients in a format that is consistent across all products, regardless of the manufacturer. The new Drug Facts label also uses language that is understood by most people. For example, "uses" is used instead of "indications," a term the FDA found was confusing to many people.¹⁸

When recommending any OTC product, including OTC homeopathic products, the clinician should counsel patients to read the Drug Facts label and, if the patient has any questions, to contact the clinician.

COMBINATION PRODUCTS

Selection of single-remedy products takes time and requires knowledge of a number of homeopathic drugs. A number of resources are available for the clinician interested in learning more about the indications for individual homeopathic medications (Table 1). However, commonly available combination prod-

TABLE 1

Resources for additional information regarding homeopathy

Resource	Contact
National Center for Complementary and Alternative Medicine: Research Report Questions and Answers about Homeopathy	http://nccam.nih.gov/health/homeopathy/homeopathy.pdf
Handbook of Nonprescription Drugs, Chapter 55: Homeopathic Medicines	American Pharmacists Association 2215 Constitution Ave. NW, Washington, DC 20037 (800) 878-0729
National Center for Homeopathy	http://nationalcenterforhomeopathy.org/
American Medical College of Homeopathy	http://www.amcofh.org/
Ontario College of Homeopathic Medicine	http://www.ochm.ca/acadint.htm

TABLE 2

Some common homeopathic agents

Ailment	Commonly used homeopathic drug	Some distinguishing characteristics/symptoms
Cold/flu/sore throat/cough/earache	Aconite	Sudden onset; first stages of cold/cough/ear infection; wakes after midnight with croupy cough or earache after exposure to dry, cold weather; external ear hot and painful; very thirsty and anxious/restless (can express fear of dying); everything tastes bitter
	Allium cepa	Nose running like when peeling an onion, irritating the nose; eyes tearing, but bland tears; tickling cough; raw feeling in throat, extending down into chest; very hungry and thirsty
	Antimonium tart	Rattling mucus in chest; difficulty expectorating; weak; gasping for breath; feels better sitting up and in cold, open room; hates to be looked at, whining
	Arsenicum	Watery, burning nasal discharge; needy and demanding, anxious/restless; very chilly; burning throat relieved by hot drinks; feels worse after midnight (1 a.m. to 2 a.m.); feels better after elevating the head; feels worse from sight or smell of food
	Belladonna	Sudden, violent onset; nose congested, but not so runny; high fever, can be agitated, delirious with fever (may scream and/or bite), flushed face, skin hot to touch; red, dry, painful throat; pupils dilated; earache with reddened ear canal or drum; throbbing, piercing, stinging pain; feels worse after jarring or washing head, especially on the right side; desires lemons or lemonade
	Bryonia	Dry hacking cough, dry throat; wants to be alone and lie very still; very thirsty for long drinks of cold water; congestive headache, holds head (to keep still) when coughing; worse in a warm room and from any motion (even chewing or swallowing)
	Chamomilla	Earache with severe, stitching pain; frantic, sensitive, extremely irritable and intolerant; thirsty; demands things, but refuses them when offered; cannot be consoled, but feels better temporarily by being carried or rocked
	Drosera	Violent, choking, painful cough with difficulty even breathing and ends in gagging or vomiting; sensation of crumbs or feather in throat; feels worse lying down and after midnight
	Eupatorium	Bone-breaking achy flu with sore back, sore eyes and headache
	Ferrum phos	Early stages with gradual onset (coming down with something—don't know what yet); irritable; inflammation, but few distinct symptoms; pale with red cheeks; short, dry, tickling cough; feels better at night; feels worse on the left side

TABLE 2 CONTINUED

Some common homeopathic agents

Ailment	Commonly used homeopathic drug	Some distinguishing characteristics/symptoms
Cold/flu/sore throat/cough/earache	Gelsemium	Summer colds; lots of sneezing; drowsy, droopy, dizzy, dull; backache and chills up and down spine; fatigue and trembling; can come on before or after anticipation anxiety (stage fright)
	Hepar sulph	Thick, yellow nasal discharge; extremely sensitive to cold, drafts and to touch, and generally very irritable; splinter-like sensation in throat and/or ear; very sensitive to pain – can wake screaming with extreme pain; constantly complaining; feels better after eating and in warmth
	Ipecac	Hacking cough with retching or vomiting; coughs with nearly every breath; excess drool; feels worse in hot, humid weather
	Kali bich	Stringy, ropy, mucousy discharge; sinus pressure – cold goes into sinusitis; croupy cough; wandering pains in small spots; desires beer and sweets; has an aversion to meat
	Mercurius	Ear and throat infections with pus, gluey, burning and foul-smelling discharge; bad breath; excess drool; condition made worse by almost everything; very sensitive to temperature changes (in either direction); suspicious; hurried
	Natrum mur	Recurrent colds after emotional upset; profuse watery nose and eyes with loss of taste and smell; dry, cracked lips with cold sore(s); desires salt and is thirsty
	Nux vom	Comes on after overindulgence in food, alcohol, drugs; nose runs during day, is stopped up at night; very sensitive to noise and smells; chilly; irritable, impatient; feels better napping and in warmth
	Phosphorus	Hard, dry, tickling cough with hoarseness; feels worse breathing cold air or talking; fearful – wants company; very thirsty for cold and carbonated drinks (which are vomited up as soon as they get warm in the stomach); feels better from sleep; desires salt and cold foods; can come on from getting wet and chilled in hot weather; outgoing, friendly, sympathetic
	Pulsatilla	Thick, yellow/yellow-green discharge from nose, eyes, ears; nose runs only in open air; fever and dry mouth, but no thirst; gentle, mild, weepy, needy for sympathy and attention; warm-blooded; feels better from open air and gently moving around; desires butter, ice cream and creamy foods, but aggravated from rich foods
	Rumex	Teasing, dry, spasmodic cough that prevents sleep; cold air excites the cough; feels worse in the evening

TABLE 2 CONTINUED

Some common homeopathic agents

Ailment	Commonly used homeopathic drug	Some distinguishing characteristics/symptoms
Cold/flu/sore throat/cough/earache	Silica	Chronic ear infections/abscesses with swollen lymph nodes; stinky feet; delicate-featured, shy, timid; eardrum can rupture; has an aversion to milk; desires eggs
	Spongia	Dry, barking cough with no wheezing or ratline; awakens feeling like suffocating – like a plug in the throat; easily exhausted; feels worse before midnight, talking or swallowing; feels better from warm drinks
Indigestion/heartburn/gas	Arsenicum	Burning pain; feels better from warm drinks; feels worse from fruit and cold drinks; can't bear sight or smell of food; thirsty for small, frequent sips; anxious – may fear dying
	Bryonia	Stitching, tearing pains; bitter regurgitation; thirsty for long drinks of cold water; irritable; feels worse from slightest motion (including eating); feels better drawing legs up
	Carbo veg	Cramping pain causing them to double over; much gas and sour belching, bloating; collapsed, weak, faint, exhausted; is cold and can even turn blue, but needs cool air moving (feels better from fanning); has an aversion to meat, milk, fatty foods
	Colocynthis	Agonizing, cutting gas pain causing them to double over; angry, easily annoyed; feels worse from fruit; feels better from hard pressure or when doubled over; can be brought on by anger
	Lycopodium	Bloated like a drum, right after eating; sensitive to pressure; lacks self-confidence, but seems bossy (performance anxiety can bring on indigestion); feels worse on right side, 4 p.m. to 8 p.m.; desires sweets and warm drinks, which relieve
	Nux vomica	Comes on a couple of hours after eating, when food won't digest and belching or passing gas are difficult; bitter or acid reflux; backache and muscle tension; irritable and impatient; competitive, Type A; can come on from overdoing it (food, drink, drugs)
	Pulsatilla	Indigestion from pork, fats, ice cream, rich foods; mild, gentle, weepy; dry mouth, but no thirst; warm-blooded; feels better in open air and gently moving around
Minor injuries Scrapes/ bruises/cuts	Calendula ointment/lotion	Soothing antiseptic qualities
	Arnica**	Fear of being touched in sore area; post-operative pain and bleeding (the remedy is always taken internally); soreness, bruising; shock from injury, but says they feel OK; helps to control internal and/or external bleeding
	Bellis perennis	Muscle soreness; injuries to deeper tissues, especially in trunk area; after major surgery

**Arnica is taken internally. It is also available as gels and ointments, but these should never be applied to an open wound.

TABLE 2 CONTINUED

Some common homeopathic agents

Ailment	Commonly used homeopathic drug	Some distinguishing characteristics/symptoms
Minor injuries/ scrapes/ bruises/cuts	Hypericum	Crushing or cutting injuries with nerve involvement; sharp, shooting pain and/or numbness or tingling
	Ledum	Puncture wounds with bruising; area cold to touch; person is chilly, but wound is better from cold applications
	Ruta	Bruising to soft tissue and bone, tendons and ligaments, especially from overstrain
	Staphysagria	Stab wounds with stitching pain; often associated with sense of humiliation, abuse or insult with anger
	Symphytum	Promotes rapid repair of broken bones
Burns	Cantharis	Second- or third-degree burns; vesicles with itching and burning; relieved by cold applications
	Causticum	Second-degree burns; burning, rawness, stitching; old burns that do not heal well
	Urtica urens	First- and second-degree burns; stinging, burning, violent itching and swelling; feels worse from cold applications

ucts do not require the same depth of knowledge and can be recommended in a process similar to that used for other OTC products.

Combination products, which include several single homeopathic drugs, are an option for otherwise healthy individuals with a common, mild-to-moderate, self-limiting illness who have a desire to use homeopathy, but do not have enough knowledge or training to use single homeopathic drugs safely and effectively. A patient can find combination products in most stores that sell OTC medications for conditions such as teething, earaches, cuts and bruises; leg cramps, colds, coughs and flu symptoms; sleeplessness, nausea, vomiting and diarrhea; vaginitis; and occasional (not chronic) headaches or seasonal allergies. Composition of homeopathic ingredients in a combination product for a specific illness usually varies from one manufacturer to another. This is just one reason why patients should be encouraged to read the Drug Facts labels carefully.

Combination homeopathic products are most commonly manufactured as tablets, but come in other dosage forms depending on the condition being treated, e.g., drops for earache or syrup for cough. These products will most likely be found on the shelf with other OTC products designed to treat a specific disorder. For example, in the sleep-aid section of one store, Calms Forte™ (homeopathic product), MidNite® (herbal blend) and Sleepinal® (diphenhydramine HCl) were located on the shelf one right next to the other. Again, patients should be encouraged to read the Drug Facts labels carefully to ensure that they are selecting the type of product they desire.

It should also be noted that some manufacturers make a variety of products, some of which are homeopathic, while others may be herbal or allopathic agents, or even some combination of the various types of ingredients. For example, products available under the brand name of Zicam® include Cough Max (active ingredient: dextromethorphan),

Cold Remedy (active ingredients: Zincum Aceticum 2X, Zincum Gluconicum 1X) and Multi-Symptom Cold and Flu (active ingredients: acetaminophen, dextromethorphan and doxylamine succinate). Again, patients should be encouraged to read the Drug Facts labels.

Homeopathic drugs used in combination products typically have potencies ranging from 3X or C to 30X or C. Probably the only exception to this is Anas Barbariae Hepatis Et Cordis Extractum, the flu remedy, found in a 200C potency in combination products. In practice, the difference between an X potency and a C potency is inconsequential. In general, higher potencies like 30C will have stronger, longer-lasting effects than 3C potencies, but this is more important to consider when using single-drug homeopathic agents and usually has little overall relevance in the efficacy of combination products.

Dosage for a combination product will vary depending on the product, its formulation and the age of the pa-

tient. These products typically contain three to nine drugs, and they are commonly taken three to four times daily; however, frequency of administration recommendation may be different depending on the potency of the formulation's ingredient and the illness being treated. The manufacturers choose the potencies they use in their formulations based on historic clinical response; the overall composition of the formula and dosing guidelines are adjusted accordingly. For acute illnesses, it is not uncommon to see instructions to dose every 15 minutes for up to x doses. Homeopathic medicines provide symptomatic relief, and dosing should be discontinued once symptoms abate.

As with conventional combination products, doses are fixed for each individual drug in the formulation, so it is important for the patient to take the medication only as directed on the label. Table 2 lists a number of ingredients found in homeopathic products for the treatment of earache, cough, common cold and sleeplessness. Table 3 provides a list of commercially available combination homeopathic products and their ingredients. As can be seen, there is variation regarding the number of ingredients in the various products. Again, as this information is available in the Drug Facts portion of the label, clinicians and patients can and should review this information when comparing products.

PATIENT CONSULTATION

A customer may want to try an OTC combination homeopathic product for his or her child's earache. The case below illustrates such a circumstance.

A young mother comes in with her young daughter, explaining that her daughter is very fussy and pulling on her right ear. The mother is concerned that her daughter may have an earache and wants to know what she should do. She has heard that

you shouldn't use antibiotics if you don't need them, but she is worried about her daughter and wants to see if there is something she can do to help her.

Based on the examination the clinician makes the following notes:

2 ½-year-old white female who presents to the office, playing with sibling in NAD Well-hydrated, irritable but consolable

T :99.0

P: 110

R: 24 and nonlabored

Skin: Pink, warm, dry; no rashes or pallor

Eyes: Conjunctiva without injection or discharge. Sclera white, nonicteric; no lesions. PERRLA; Fundoscopic—normal

Ears: Canals—pale white, no erythema or discharge. TM's—Right TM: pale pink, bony landmarks visible, cone of light at 5, moves with insufflation; no bulging or perforation. Left TM—pearly gray; bony landmarks visible, cone of light at 7, moves with insufflation; no bulging or perforation

Nose: Mucosa pale pink; no erythema. + clear discharge. Inferior turbinates pink without erythema

Mouth: Moist mucosa; Tonsils pink; no erythema or discharge

Nodes: Nonpalpable, nontender

Lungs: Clear bilaterally; no crackles, wheezes or rubs

Heart: S1, S2, RRR, no S3 or S4. No murmurs

Abdomen: Soft, + bowel sounds. No tenderness, masses, rebound or guarding

Neuro: Awake and alert; no abnormalities noted. Negative Kernig and Brudzinski sign

A: Acute Otitis Media

P: Watchful waiting is appropriate

This case illustrates the perfect situation for using a combination homeopathic drug. The patient has obvious signs of a beginning ear infection; however, her

symptoms are mild, and she has not yet manifested any serious signs of an infection, e.g., otorrhea or high fever. The mother did not indicate any problems with the child's hearing or a loss of balance either. Furthermore, the child does not have a history of any ear infections or disease, so the condition at hand is uncomplicated and does not represent a chronic condition.

The mother's desire to avoid use of antibiotics is well-founded. The clinical practice guidelines published jointly by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) acknowledge concerns about the rising rates of antibacterial resistance, the growing costs of antibacterial prescriptions and the need for judicious use of antibacterial agents.¹⁹ Moreover, they cite the difficulty associated with differentiating between acute otitis media (AOM) and otitis media with effusion (OME) in young children and infants, and the concern that a mistaken diagnosis may lead to unnecessary prescribing of antibiotics, as antibiotics are indicated for AOM, but not for OME. As such, criteria were developed based on age and certainty of diagnosis. The recommendations are that for children ages 6 months to 2 years with an uncertain diagnosis of AOM, antibacterial therapy is only indicated if severe illness is present; 48-hour observation, known as the "watchful waiting" or "wait and see" period, is appropriate when follow-up can be ensured. Antibiotic therapy should be started if symptoms persist or worsen. Severe illness is defined as moderate to severe otalgia or fever $\geq 39^{\circ}\text{C}$ (102.2°F). The recommendation for children younger than 6 months old with a certain diagnosis of AOM is antibacterial therapy. For children 2 years of age or older, antibiotics are only indicated in severe disease; observation is an option if the illness is milder.¹⁹

Given the circumstances of the case above and the recommendations of the AAP and the AAFP, the health practi-

TABLE 3

Ingredients and purpose information from Drug Facts Label of example combination homeopathic products

Brand	Product	Ingredients	Purpose
<i>Earache</i> Hyland's	Earache drops	Pulsatilla 30C	Ear pain worse at night
		Chamomilla 30C	Restlessness and irritability
	Earache tablets	Sulphur 30C	Throbbing ear pain
		Calcarea carbonica 30C	Ear pain with burning
		Belladonna 30C	Fever and inflammation
		Lycopodium 30C	Pain and congestion
		Citric acid, purified water, sodium benzoate, vegetable glycerine (drops) lactose (tablets)	Inactive ingredients
Murine	Earache relief Ear drops	Chamomilla 10X	Calmative, pain reliever
		Mercuris solubilis 15X	Anti-inflammatory
		Sulphur 12X	Pain reliever, anti-itch
		Lydopodium 8X	Hearing support
		Benzalkonium Cl, glycerine	Inactive ingredient
Similisan	Earache relief Ear drops	Chamomilla 10X	Calmative, pain reliever
		Sulphur 12X	Pain reliever, anti-itch
		Mercurius solubilis 15X	Anti-inflammatory, pain reliever
		Pulsatilla 12X (in children's formulation only)	Pain reliever for pain worse at night, calmative
		Glycerin	Inactive ingredients
<i>Cough syrups</i> Boiron	Chestal Honey*	Antimonium tartaricum 6C	Helps loosen thick mucus
		Bryonia alba 3C	Relieves dry and painful cough
		Coccus cacti 3C	Relieves cough associated with a tickling in the throat
		Drosera rotundifolia 3C	Barking cough worse at night
		Ipecacuanha 3C	Relieves cough associated with nausea
		Pulsatilla 6C	Relieves wet cough during the day that becomes dry at night
		Rumex crispus 6C	Relieves dry cough triggered by cold air
		Spongia tosta 3C	Relieves dry, croupy and barking cough
		Sticta pulmonaria 3C	Relieves nighttime hacking cough
		Honey, sucrose, citric acid, sodium benzoate	Inactive ingredients

*Note: Honey should not be used in children younger than 1 year old

TABLE 3 CONTINUED

Ingredients and purpose information from Drug Facts Label of example combination homeopathic product

Brand	Product	Ingredients	Purpose
<i>Cough syrups</i> Hyland's	Cough Syrup with Honey*	Ipecacuanha 6X	Spasmodic, gagging cough Dry, barking cough
		Aconitum napellus 6X	Hoarse, dry, croupy cough with sudden onset
		Spongia tosta 6X	Dry barking croupy coughs that are nonproductive
		Antimonium tartaricum 6X	Rattling cough
		Honey syrup base, orange honey, purified water, cane sugar, vegetable glycerine, sodium benzoate	Inactive ingredients
<i>Cold</i> Boiron	Coldcalm tablets	Allium cepa 3C	Relieves sneezing and runny nose
		Apis mellifica 6C	Relieves nasal congestion
		Belladonna 6C	Relieves colds with a sudden onset
		Eupatorium perfoliatum 3C	Relieves sinus pain
		Gelsemium sempervirens 6C	Relieves headache associated with cold
		Kali bichromicum 6C	Relieves nasal discharge
		Nux vomica 3C	Relieves sneezing attacks
		Phytolacca decandra 6C	Relieves sore throat associated with colds
		Pulsatilla 6C	Relieves colds with a loss of taste and smell
		Lactose, croscarmellose sodium, magnesium stearate	Inactive ingredients
Humphrey's	Humphrey's No. 77 tablets	Arsenicum album 6X	Antihistaminic
		Gelsemium sempervirens.3X	Fever reducer
		Allium cepa 3X	Antihistaminic
		Aconitum napellus 3X	Cough suppressant
		Sugar, corn starch, stearic acid	Inactive ingredients
Hyland's	Hyland's C-Plus cold tablets	Eupatorium perfoliatum 3X	Headache, vomiting cough, sneezing
		Euphrasia officinalis 2X	Runny eyes and nose
		Gelsemium sempervirens 3X	Sneezing with stuffy nose, difficulty swallowing, swallowing causes pain in ear
		Kali Iodatum 3X	Headache, runny eyes and nose
		Lactose	Inactive ingredient

*Note: Honey should not be used in children younger than 1 year old

TABLE 3 CONTINUED

Ingredients and purpose information from Drug Facts Label of example combination homeopathic products

Brand	Product	Ingredients	Purpose
<i>Cold</i> Similisan Healthy Relief	Cold Reduce lozenges	Allium cepa 10X	Runny nose, chest congestion, sneezing, sore throat, cough
		Kali bichromicum 8X	Runny nose, sneezing, sinus/nasal congestion, cough
		Luffa operculata 8X	Headache, runny nose
		Zincum oxydatum 1X	Reduces the duration and severity of the common cold
		Adipic acid, dextrose, glycer- ine, magnesium stearate, natu- ral orange flavor, silica gel	Inactive ingredients
Zicam	Cold Remedy	Zincum aceticum 2X	Reduces duration and severity of the common cold
		Zincum gluconicum 1X	Reduces duration and severity of the common cold
		FD&C red 40, glycerin, HPMC, lecithin, maltitol syrup, maltodextrin, mono and di-glycerides, natural and artificial strawberry flavor, partially hydroge- nated cotton seed and soy oil, sugar	Inactive ingredients
<i>Sleeplessness</i> Boiron	Quietude tablets	Hyoscyamus niger 3X	Restless sleep associated with nervousness
		Nux moschata 4C	Relieves restless sleep
		Passiflora incarnata 3X	Relieves sleeplessness associated with worries and exhaustion
		Stramonium 6X	Relieves sleeplessness with inter- mittent awakening
		Lactose, croscarmellose so- dium, magnesium stearate	Inactive ingredients
Hyland's	Calms Forté tablets	Avena Sativa 1X double strength	Stress and nervousness
		Chamomilla 2X	Nervous irritability
		Humulif Lupulus 1X double strength	Drowsiness with incomplete sleep
		Passiflora 1X triple strength	Restless or wakeful sleep from exhaustion

TABLE 3 CONTINUED

Ingredients and purpose information from Drug Facts Label of example combination homeopathic products

Brand	Product	Ingredients	Purpose
<i>Sleeplessness</i>			
Hyland's (cont'd)	Calms Forté tablets	Calcarea Phosphorica 3X	Enhancing cellular function
		Ferrum Phosphoricum 3X	Enhancing cellular function
		Kali Phosphoricum 3X	Enhancing cellular function
		Natrum Phosphoricum 3X	Enhancing cellular function
		Magnesia Phosphoricum 3X	Enhancing cellular function
		Lactose, calcium sulfate, starch, magnesium stearate	Inactive ingredients

tioner can safely recommend an OTC homeopathic product. However, it is extremely important that when utilizing the “wait and see” period as indicated in the guidelines, that the clinician also reinforces the importance of timely follow-up if the child’s symptoms worsen.

Patients who are interested in homeopathic treatment of chronic conditions can be referred to a professional homeopath who can determine which single homeopathic medication(s) will be best for them for long-term management. In chronic otitis media or complex cases, it is important to identify possible causes of recurrent disease and to establish a definitive diagnosis of acute episodes. Working with a certified homeopathic provider in cases where a patient wants to pursue homeopathic treatment can be enlightening and rewarding for any health care practitioner. To find a certified homeopathic practitioner, many of which are board-certified M.D.’s, D.O.’s and N.D.’s, the National Center for Homeopathy provides a Web-based directory on its Web site at <http://nationalcenterforhomeopathy.org/resources/practitioners.jsp>.

SIDE EFFECTS AND ADVERSE REACTIONS ASSOCIATED WITH HOMEOPATHIC DRUGS

The desired response to homeopathic medication is, of course, for the symp-

toms to resolve smoothly and more rapidly than they would have without treatment. Furthermore, the claim is often made that homeopathic drugs do not cause side effects. Yet people can have reactions to homeopathic medications for various reasons – including allergies to milk or other excipients used in the formulations. However, in contrast to conventional medications, side effects from homeopathic drugs are not generally life-threatening and are associated with various aspects of the healing process. It is important to emphasize to consumers, however, that homeopathic medicines should not be repeated too frequently, particularly when improvement is under way, because this may overstimulate their system. Such a reaction to homeopathic medication is called an aggravation, which means a temporary intensification of the symptoms being treated.

Homeopathic aggravations can happen if the medicines are taken too frequently or when high potencies (200C or greater) are used; however, in the rare individual who is extremely sensitive, they may occur even with lower potencies, as is found in combination homeopathic products. When such a reaction occurs, the remedy should be discontinued and the homeopathic practitioner consulted. If any reaction to homeopathic treatment

escalates to a life-threatening intensity, emergency medical attention should be sought.

Allergic reactions to homeopathic potencies greater than 24X or 12C are extremely unlikely (because they surpass molecular ranges). However, very sensitive individuals could conceivably have an allergic response to a low-potency homeopathic drug (<12C), even though it might not contain enough substance to provoke a true pharmacologic drug reaction. So, for example, a person who is extremely allergic to bee stings might want to avoid taking *Apis mellifica* (derived from honeybee) at a potency lower than 12C.

OTC homeopathic medicines are labeled with a warning for pregnant or nursing mothers to seek the advice of a health professional before using the product. There has been no research indicating potential harm in these circumstances, however, and the warning is simply a standard precaution. Homeopathic practitioners specializing in obstetric care commonly use homeopathic drugs in their practices and would be good sources of advice for pregnant consumers.

Just like conventional pharmaceutical medications, homeopathic products may contain lactose (oral dosage forms) or alcohol (liquid formulations), so patients

with lactose intolerance or restrictions to alcohol ingestion should be counseled according to the severity of their intolerance. Homeopathic agents can be found or made using a glycerin base instead of lactose or alcohol.

The potential for drug interactions with homeopathic medicines is remote. Any pharmacokinetic interaction between homeopathic and pharmaceutical drugs can be confidently ruled out when potencies of greater than 12C or 24X are used, because these potencies contain virtually no molecules of material substance to interact with a pharmaceutical drug. However, it may be prudent to monitor patients taking drugs with a low therapeutic index or when a significant interaction exists between a conventional pharmaceutical medication and an ingredient in a combination product if that ingredient is in a very low potency.

QUESTIONS REGARDING BENEFITS OF HOMEOPATHY

Some health care providers question the efficacy of homeopathic medicines. And, as with many treatments, the medical literature is mixed.²⁰⁻²³ Challenges to homeopathy are often based on the following issues: 1) Most homeopathic preparations do not contain sufficient

material substance to elicit a pharmacological effect; and 2) There are insufficient double-blind, placebo-controlled clinical trials demonstrating efficacy for all of the homeopathic remedies used for the myriad of indications in which they are believed to be effective.

Despite the difficulties of limited research funding and in designing scientific studies that maintain the integrity of homeopathy's fundamental laws and principles, especially with respect to individualizing drug therapy and dosing regimens, a substantial number of double-blind and/or randomized, placebo-controlled trials have been performed for a number of homeopathic drugs in a number of indications. In a meta-analysis conducted by Linde et al²⁰ of 119 randomized and/or double-blind, placebo-controlled trials, the clinical effects of homeopathic treatment in general could not be attributed solely to placebo, but the efficacy could not be clearly established for any single clinical condition. Mathie²¹ reviewed 93 randomized and/or double-blind controlled trials comparing homeopathy with either placebo or another treatment. Fifty of the studies reported a significant benefit of homeopathy in at least one clinical outcome measure, while 41 failed to discern significant intergroup differences, and two

described an inferior response with homeopathy.

Allergic rhinitis and childhood diarrhea have been investigated by repeated controlled clinical trials. A randomized placebo-controlled study reproduced the results of four previous studies testing the effects of homeopathically prepared allergens (30C) in patients with allergic rhinitis or asthma.²² Similar to the previous three studies, nasal airflow was significantly ($p = .0001$) improved with homeopathic treatment compared with the placebo. Childhood diarrhea has been studied in a series of three high-quality, double-blind, placebo-controlled studies by Jacobs et al.²³ The meta-analysis showed that homeopathic treatment reduced the duration of diarrhea from 4.1 days to 3.3 days ($p = 0.008$).

CONCLUSION

Homeopathy has broad application for patient care needs, and it offers the clinician many opportunities to serve patients who need assistance in choosing and managing these medications correctly. Moreover, as many patients use homeopathic medications, it is important that all health care professionals are prepared to work with these patients and provide care within the full context of their needs and preferences.

¹Johnsen M. Top 150 Niche: Niche offers unique solutions with high-margin potential. *Special Report. Drug Store News*; 2007; May 21:19-20. ²Traynor K. Nonprescription cold remedies unsafe for young children, FDA advisers say. *Am J Health Syst Pharm*. 2007; 64: 2408-2410. ³CDER. Questions and Answers Safety of Phenylpropranolamine. Available at <http://www.fda.gov/cder/drug/infopage/ppa/qa.htm>. Accessed November 20, 2007. ⁴Johnson T, Boon H. Where does homeopathy fit in pharmacy practice? *Am J Pharm Educ*. 2007 Feb 15;71(1):7. ⁵National Center for Complementary and Alternative Medicine, National Institutes of Health. Research Report. Questions and Answers About Homeopathy. Available at: <http://nccam.nih.gov/health/homeopathy/#a1>. Accessed November 19, 2007. ⁶De Schepper L. Hahnemann Revisited A Textbook of Classical Homeopathy for the Professional..SantaFe, NM, Full of Life Publications. 1999:xiv-xix. ⁷Swayne J. Ed. Churchill Livingstone's International Dictionary of Homeopathy. London, UK, Churchill Livingstone, 2000:106. ⁸Winston, J. The Faces of Homeopathy: An Illustrated History of the First 200 Years. Tawa, New Zealand, Great Auk Publishing. 1999:85. ⁹Neustaedter R. Homeopathy and the flu: A proven track record against the flu. What homeopathy can do for you. *Homeopathy Today*;2004; Nov/Dec:16-18. ¹⁰American Association of Homeopathic Pharmacists Fact Sheet. Distribution. Accessed December 3, 2007. Available at: <http://www.homeopathyresource.org/industry/factsheet.php>. ¹¹Swayne J. Homeopathic Method: Implications for Clinical Practice and Medical Sciences. New York, New York, Churchill Livingstone, 1998:20-2, 164-165. ¹²Cummings S, Ulman D. Everybody's Guide to Homeopathic Medicines. New York, New York, Penguin Putnam Inc.; 1996:17-18. ¹³Homeopathic Pharmacopoeia of the United States. Southeastern, Pa: Homeopathic Pharmacopoeia Convention of the United States; 2007. ¹⁴Borneman JA III, Borneman JP. Practical Homeopathic Pharmacy. National Center for Homeopathy Summer Homeopathy Courses, John Hopkins University; June 25, 2001; Baltimore, MD. ¹⁵Reidlinger J, Lennihan J. Homeopathic Medicines, Chapter 55. In: Berardi RR, et al, eds. *Handbook of Nonprescription Drugs: An Interactive Approach to Self-care*, 14th Ed. Washington, DC: American Pharmaceutical Association; 2004:1305-1336. ¹⁶FDA/ORA CPG 7132.15. Sec. 400.400. Conditions under which homeopathic drugs may be marketed (CPG 7132.15). Available at: http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg400-400.html. Accessed February 22, 2005. ¹⁷Stehlin I. Homeopathy: Real Medicine or Empty Promises? Accessed on December 12, 2007. Available at http://www.fda.gov/fdac/features/096_home.html. ¹⁸U.S. Food and Drug Administration FDA Consumer magazine July-August 2002 http://www.fda.gov/fdac/features/2002/402_etc.html. Accessed 1/18/08. ¹⁹Subcommittee on Management of Acute Otitis Media. Clinical practice guidelines: diagnosis and management of acute otitis media. *Pediatrics*. 2004;113 (5):1451-1465. ²⁰Linde K, Clausius N, Ramirez G et al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* 1997; 350(9081): 834-843. ²¹Mathie RT. The research evidence base for homeopathy: a fresh assessment of the literature. *Homeopathy* 2003; 92(2):84-91. ²²Taylor MA, Reilly DT, Llewellyn-Jones RH, et al. Randomized controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series. *Brit Med J* 2000; 321:471-6. ²³Jacobs J, Jonas WB, Jiménez-Perez M, et al. Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials. *Pediatr Infect Dis J*; 2003;22(3):229-34.

Combination Homeopathy Products in the Retail Setting

Learning Assessment

Successful completion of “Combination Homeopathy Products in the Retail Setting,” is accredited for 1.5 contact hours of credit. To obtain credit, answer the following questions and complete the evaluation online at www.retailclinician.com.

- Homeopathic medicines have been used in the United States and overseas for at least:
 - 50 years
 - 100 years
 - 150 years
 - 200 years
- A pharmacist can distinguish between a homeopathic OTC product and an herbal OTC product by checking:
 - the name of the ingredients
 - the strength of the ingredients
 - the number of ingredients
 - the term remedy used on the packaging information
- What is the name of the process used to make homeopathic drugs in which a substance is serially diluted and succussed (or triturated) to increase its strength or potency?
 - strengthening
 - fortification
 - attenuation or potentization
 - concentration
- Which statement is true about the regulation of homeopathic drugs in the United States?
 - They are regulated under the Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. § 201.
 - They are regulated in the same way that herbal OTC products are.
 - Homeopathic products containing alcohol are not regulated by the Federal Trade Commission or the Bureau of Tobacco, Alcohol and Firearms.
 - They are not regulated by any federal organization.
- The Homoeopathic Pharmacopoeia of the United States (HPUS) is best described as:
 - a materia medica that contains detailed information about substances and their attributes
 - a repertory containing a list of symptoms and associated homeopathic drugs
 - an official compendium like the National Formulary or the United States Pharmacopoeia that define the term drug as an article recognized in these texts
 - a homeopathic dictionary
- Who was the first to market combination homeopathic drug products in the United States in 1854?
 - Samuel Hahnemann
 - Frederick Humphreys
 - James Tyler Kent
 - Constantine Hering
- OTC combination homeopathic products:
 - are intended primarily for home use by nonprofessionals
 - do not require the individualization necessary for single homeopathic therapies
 - cover a variety of “pictures” that are typical of a particular condition
 - all of the above
- OTC homeopathic product labeling must include Drug Facts information.
 - True
 - False
- OTC homeopathic product labels are required to include an expiration date.
 - True
 - False
- Clinical guidelines published by the American Academy of Pediatrics and the American Academy of Family Physicians indicate that all suspected cases of AOM should receive immediate treatment with antibiotics.
 - True
 - False