

Echinacea and Truth in Labeling

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Background: *Echinacea* sales represent 10% of the dietary supplement market in the United States, but there is no guarantee as to the content, quality, variability, or contamination in *Echinacea* preparations.

Objective: To qualitatively and quantitatively assess the contents of *Echinacea*-only preparations available in a retail setting.

Methods: One of each single-herb *Echinacea* preparations that were available in August 2000 was obtained from several stores in the Denver, Colo, area. Thin-layer chromatography (TLC) was used to determine species and measure quantity. From this information, accuracy of species labeling and comparison of constituent to labeled content were assessed. The samples were stratified by whether they were labeled as standardized, and

the standardized and nonstandardized samples were compared by ratio of constituent to labeled content.

Results: Of the samples, 6 (10%) of 59 preparations contained no measurable *Echinacea*. The assayed species content was consistent with labeled content in 31 (52%) of the samples. Of the 21 standardized preparations, 9 (43%) met the quality standard described on the label. Labeled milligrams were weakly associated with measured constituent ($r=0.35$; $P=.02$).

Conclusions: *Echinacea* from retail stores often does not contain the labeled species. A claim of "standardization" does not mean the preparation is accurately labeled, nor does it indicate less variability in concentration of constituents of the herb.

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SALES OF HERBS and phyto-medicines in the United States have exploded in recent years. Americans spent \$5.1 billion in 1997 on herbal medicines, nearly a 4-fold increase since 1990.¹ Sales of *Echinacea* represent 10% of the total US market in herbal medicines.² Most herbal products are used to treat minor conditions and illnesses in much the same manner as conventional Food and Drug Administration (FDA)-approved over-the-counter medicines. Herbal medicines are not subject to FDA evaluation and approval; however, there are no assurances as to whether an herbal medicine works, what portion of the herb has the effect, whether that portion is present in an herbal medicine in any measurable quantity, or that the label reflects the content.

Echinacea has become popularly regarded in the United States as a treatment for the common cold and an "immune system booster." However, most consumers are not aware that products

they buy that are labeled *Echinacea* can be biochemically distinct, with different clinical efficacies. This is due to the use of 3 species of *Echinacea* interchangeably; the use of different plant parts; different methods of harvest, preparation, and extraction; and the addition of extracts of other plants. In Germany, where herbal medicines are used extensively and are paid for by health insurance, a commission (Commission E) was established to review data about herbs and has supported only the use of *Echinacea pallida* root and *Echinacea purpurea* plant for treating colds and for bolstering the immune system.^{3,4}

Over 30 clinical studies and in vitro studies have been published about *Echinacea* to date. Though clinical data are limited, *E purpurea* may decrease symptom severity of the common cold and may decrease the number of colds when taken prophylactically,^{5,6} and *E pallida* root extract may decrease the duration of symptoms of the common cold.⁷ More conflicting data exist about *Echinacea angustifolia*, and while some clinical data suggest it may

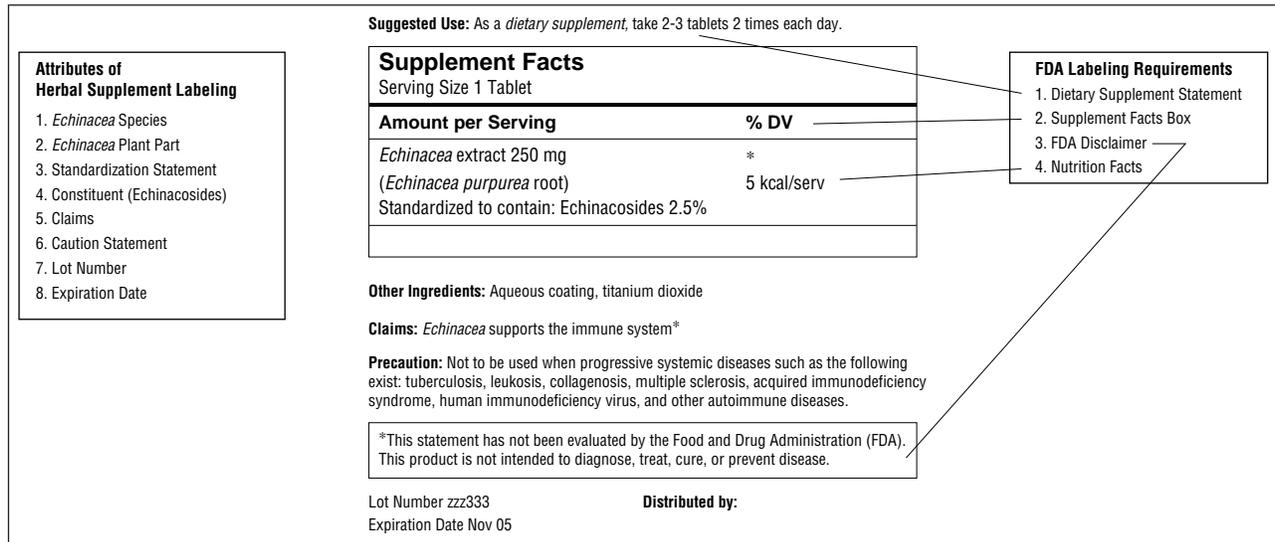


Figure 1. Anatomy of an *Echinacea* label. This diagram is fictitious. It is a composite of many different label attributes. The caution statement is taken directly from the German Commission E monograph for *Echinacea pallida* root (August 29, 1992).³

decrease symptom severity of the common cold, some show it may not,^{8,9} and it is not currently approved by the German Commission E.¹⁰ In vitro studies of the effect of *Echinacea* have also demonstrated differences in the efficacies of hydrophilic and lipophilic extracts of distinct plant parts of each species.¹¹

Many herbal preparations use the term “standardization” to imply that an herb is uniformly comparable with other preparations of the same herb. We undertook this study to examine whether the species content of retail preparations of *Echinacea* agreed with the labeled content and whether the labeling claim standardized indicated a better association between milligrams of constituent and labeled milligrams of herb than those not so labeled.

METHODS

STUDY DESIGN

We purchased single-herb preparations of *Echinacea* from retail outlets in the Denver, Colo, area on 2 days in August 2000. Only single-herb *Echinacea* preparations were included so that qualitative and quantitative assessments could be carried out without contamination from other ingredients. All dosage forms were eligible for inclusion, whether tablet, caplet, capsule, liquid, powder, or granule. The retail outlets were chosen from a range of stores that met the FDA-identified classes of retail venues of dietary supplements.¹² When possible, 2 or 3 stores from each company were visited on 2 separate occasions to ensure a complete sampling. From these venues, 59 products were purchased.

OUTCOME MEASURES

Labels were assessed for listing of species and plant part, milligrams of herb, price, dose, form, recommended daily dose, and claims of standardization. Claims made for the herb’s activity were separated into categories of statements, including “research supported” the use of *Echinacea* during cold and flu season, or that *Echinacea* “supported,” “enhanced,” or otherwise improved the immune system, or that *Echinacea* was a “di-

etary supplement.” We assessed each sample for a “caution statement” or mention of the contraindications for the use of an herb, which may include allergies to daisies, autoimmune disease, human immunodeficiency virus, tuberculosis, collagen-vascular disease, and multiple sclerosis^{10,11} We also assessed conformity of the labeling with FDA recommendations (**Figure 1**).¹² A compliance score was generated for each of the 4 FDA recommendations that the label met. The supplements were then placed into numbered containers and sent to S&W Microchemical Laboratories, East Lyme, Conn. The laboratory analysts were blinded to the source and labeled content of all samples. Thin-layer chromatography (TLC) was used for qualitative analysis. For quantitative analysis, cichoric acid and echinacoside were measured and compared with standard preparations. Cichoric acid and echinacoside are 2 substances found consistently in different species of *Echinacea*, which may be used to differentiate species. Cichoric acid is found consistently in all plant parts of *E purpurea*, and echinacoside is found in *E angustifolia* and *E pallida*.¹³ Only 5 of 59 samples were labeled as containing *E pallida* and were not labeled as *E angustifolia*; therefore, differentiation between *E angustifolia* and *E pallida* was never a concern. Because some samples contained more or fewer species than stated on the label, a composite measurement was created of total weight of the constituents in milligrams that the sample was supposed to contain according to the label. For example, if the sample was labeled as containing only *E purpurea* but contained echinacoside as determined by assay, echinacoside was not counted toward the weight of constituent in the comparison because echinacoside is not present in *E purpurea*.

LABORATORY ANALYSIS

Qualitative identification of *E purpurea*, *pallida*, and *angustifolia* using TLC has been well described by Bauer and Remiger¹⁴ and Wagner.¹⁵ The content of each band on TLC has also been described by Bauer and Remiger¹⁴ for each *Echinacea* species. In the present study, TLC analysis of the samples was carried out in accordance with their methods. Tincture samples were analyzed in original form or as a 1:5 or 1:100 dilution. Capsules and coated samples were opened, the contents removed and combined, and 200 mg of milled sample was transferred to a reaction vial containing 4 mL of solvent consisting of methanol-water solution (80:20). Hard or pliable coated samples were

ground in a mortar, and 200 mg of sample was transferred to a reaction vial containing 4 mL of the same solvent. Capsules and coated samples were refluxed at 60°C for 60 minutes and then shaken for 12 hours. The samples were allowed to settle and then the supernatant was transferred to a permanent vial. This supernatant was either analyzed without further dilution or with a 1:5 dilution with a methanol-water solution (80:20) if the concentration was too high for the quantitative assay. Thin-layer chromatography was performed using Macherey-Nagel Durasil-20 UV254 10 × 20-cm plates (Macherey-Nagel GmbH, Düren, Germany), with a mobile phase of ethyl acetate, formic acid, acetic acid, and water in a 100:11:11:27 ratio. Development was vertical with chamber saturation. Detection was performed with diphenylboryloxyethylamine-polyethylene glycol reagent at UV 366 nm. For quantitative analysis, standards of cichoric acid and echinacoside were obtained from the Labors Addipharma division of PhytoLab in Hamburg, Germany. Both standards were processed with the samples on each TLC plate. Reflective absorbance from the TLC plates was measured and compared with the intensity of the prepared standard curve to provide a proportional indication of weight in milligrams of constituents. The detection limit of the echinacoside was 0.13% for the pill forms and 66 µg/mL for tinctures, with a procedural SD of ±0.2 mg. The detection limit of cichoric acid was 0.05% for pill form and 24 µg/mL for the tinctures, with a procedural SD of ±0.1 mg. Cichoric acid and echinacoside levels for 2 samples were below the detection limit, and while there was pattern present for identification, these samples were excluded from the quantitative comparison.

STATISTICAL ANALYSIS

All analyses were performed with SAS software (version 8.0, SAS Institute, Cary, NC). To compare standardized and non-standardized preparations, the χ^2 and Fisher exact tests were used for categorical data. The *t* test was used for comparing continuous or ordinal data, and Pearson correlation coefficients were used for assessing the association between labeled and measured milligrams. The Mantel-Haenszel χ^2 was used for comparison of stratified data.

RESULTS

Fifty-nine samples were obtained from 11 stores (**Table 1**). Of the 59 samples purchased, 21 (36%) were labeled as standardized. The recommended daily doses were widely distributed, ranging from 45 to 1600 mg in the standardized group, to 100 to 5380 mg in the non-standardized preparations. The German Commission E recommends a dose of 900 mg/d. Of the samples, 14 (24%) had recommended doses higher than the Commission E. The retail cost per labeled daily dose of the standardized preparations ranged from \$0.07 to \$1.33 compared with \$0.02 to \$2.99 in the nonstandardized preparations.

Only 4 (7%) of the samples met all 4 of the FDA's labeling requirements (Table 1). The standardized samples (mean score, 2.6) had better labeling compliance than nonstandardized preparations (mean score, 1.8) ($P=.05$). The greatest difference in requirements was the presence of the "Supplements Facts" box. Claims about the activity of *Echinacea* were made in 16 (76%) of 21 preparations labeled as standardized and 21 (55%) of 38 nonstandardized preparations. Forty-seven of the samples (80%) had expiration dates, and 28 (47%) had caution

Table 1. Characteristics of *Echinacea* Samples Purchased for Study (N = 59)*

Retail outlet category	
Grocery	11 (19)
Health food store	18 (31)
Vitamin/herb store	22 (37)
Drug store	6 (10)
General merchandiser	2 (3)
Distribution form	
Tablet	9 (15)
Capsule	32 (54)
Softgel	4 (7)
Liquid	14 (24)
Standardized samples	21 (36)
Caution statement	28 (47)
Expiration date	47 (80)
FDA labeling requirements, mean ± SD score†	2.08 ± 1.21
Had all 4 statements	4 (7)
No claims	22 (37)
Dose recommended (range), mg	45-5380
Price per recommended dose (range), \$	0.02-2.99

*Data are number (percentage) of samples unless otherwise indicated.
†Food and Drug Administration (FDA) labeling regulations: 1 point for each of the 4 regulations.

statements. All of the samples analyzed were analyzed before the expiration date.

In 2 samples from each group, no species designation could be found on the label, so these were excluded from the qualitative analysis. As determined by TLC, 6 samples contained no measurable *Echinacea*. All of these samples were from the nonstandardized group and were excluded from further analysis (**Table 2**). The content of 31 (52%) of the samples agreed with the content listed on the label. Of the 18 samples in which content did not agree with the label, 7 (39%) of the samples contained more species than were listed on the label, and 10 (56%) had fewer species than listed in the label. Among the non-standardized samples, 1 preparation contained a substitution of *E angustifolia* for *E purpurea* and 3 had substitutions of *E purpurea* for *E angustifolia*. The standardized samples contained more or fewer species than the label but had no direct substitutions of species.

The average number of milligrams specified on the label was significantly more in the nonstandardized group than in the standardized group. Nine samples had no milligrams of *Echinacea* listed on the label. While the labeled milligrams in the nonstandardized group were almost twice the labeled milligrams in the standardized group, the proportion of labeled to measured milligrams was not statistically different between the 2 groups (Table 2).

Plots were made to assess the linear correlation between the measured and labeled milligrams (**Figure 2**). Samples with no milligrams of *Echinacea* on the label were excluded from this analysis. The correlation coefficient for all samples was 0.34 ($P=.02$), and while the correlation was statistically significant, the magnitude of the coefficient was not consistent with a strong association. The standardized samples had a higher correlation coefficient ($r=0.49$; $P=.02$) than the nonstandardized ($r=0.21$; $P=.28$), but there was no difference between the corre-

Table 2. Comparison of Species Listed on Label With Species Detected by Assay*

	All, No. (%) (N = 59)	Standardized, No. (%) (n = 21)	Nonstandardized, No. (%) (n = 38)	P Value
No species on label	4 (7)	2 (10)	2 (5)	.61
None detected	6 (10)	0	6 (15)	.08
Qualitative Comparison				
	All, No. (%) (n = 49)	Standardized, No. (%) (n = 19)	Nonstandardized, No. (%) (n = 30)	P Value
Content matched label	31 (63)	10 (53)	21 (70)	.23
Content did not match label	18 (37)	9 (47)	9 (30)	.23
Quantitative Comparison				
	All, Mean ± SD (n = 47)	Standardized, Mean ± SD (n = 19)	Nonstandardized, Mean ± SD (n = 28)	P Value
Labeled milligrams†	367.17 ± 259.71	221.4 ± 129.8	484.92 ± 279.9	<.001
Constituent milligrams of cichoric acid‡	1.67 ± 1.87	0.90 ± 1.09	2.30 ± 2.14	.006
Echinacoside§	3.31 ± 4.79	1.59 ± 2.89	5.33 ± 5.83	.06
Combined	3.52 ± 3.88	1.97 ± 2.00	4.78 ± 4.31	.009
Milligrams of combined measured constituent per labeled milligrams of herb	0.011 ± 0.016	0.006 ± 0.016	0.009 ± 0.007	.19

*The terms standardized and nonstandardized refer to label claims.

†Fifty samples had labeled milligrams.

‡Fifty samples contained cichoric acid, a constituent of *Echinacea purpurea*.

§Twenty-eight samples contained echinacoside, a constituent of *Echinacea angustifolia* and *Echinacea pallida*.

||Determined as milligrams of constituent(s) the sample should contain appropriate to labeled species.

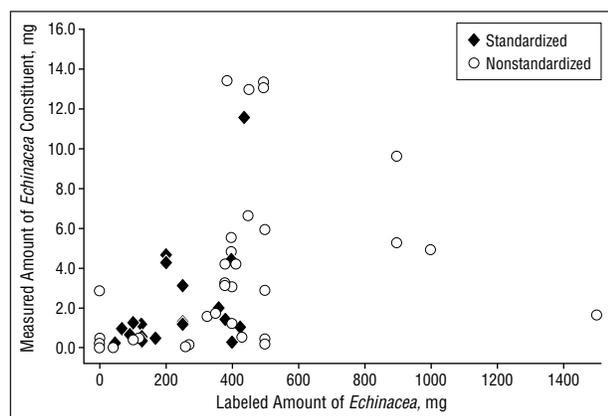


Figure 2. Comparison of labeled milligrams *Echinacea* to measured milligrams constituent. All samples: $r=0.34$; $P=.02$. Standardized samples: $r=0.49$; $P=.02$. Nonstandardized samples: $r=0.21$; $P=.28$.

lation coefficients of the standardized and nonstandardized preparations ($P=.59$).

Of the samples labeled as standardized, 18 (86%) listed the constituent and amount that was used for the standard. Labels of 2 of the nonstandardized samples stated a quantity of constituent that they contained but did not say that the sample was standardized to that constituent. Of the samples with a labeled standard, 9 identified cichoric acid or echinacoside as the standard and could be compared with our quantitative assessment. None of those samples contained as much constituent as specified in the labeled standard. Two samples did not contain a measurable level of the constituent labeled as the standard. The other 7 contained a mean of 26% of the labeled standard. Labels on 10 of the

samples stated they were standardized to phenolics, which are a large group of bands on TLC that contain both cichoric acid and echinacoside. In *E purpurea* the main component of the phenolic band is cichoric acid and in *E angustifolia* the main component is echinacoside. The constituents we measured should have comprised most of the phenolic standard on the label,¹³ but those samples contained a mean of only 21% of the labeled standard.

The expected concentration of cichoric acid in *E purpurea* plants in nature ranges from 0.52% to 2.27% depending on when the plant is harvested and what plant part is used.¹⁶ The concentration of cichoric acid in the present study ranged from 0% to 1.46%, and 37% of the samples had cichoric acid levels within the expected range. The natural concentration of echinacoside in *E angustifolia* in nature ranges from 0.18% to 0.82%.¹⁷ There are no known natural levels of echinacoside for *E pallida*. Only 7 of the samples expected to contain echinacoside had levels that fell within the expected range. Eight samples contained 2 to 4 times the upper limit of normal described by Perry et al.¹⁷

COMMENT

Echinacea samples available for purchase in Denver in August 2000 did not reliably contain the labeled species. Those samples labeled as “standardized” were not significantly more likely to contain the labeled species than those not standardized. The correlation between the labeled milligrams of herb and the measured milligrams was weak in both standardized and nonstandardized preparations. The claim that a sample was standardized

indicated that the constituents of a sample correlated with the milligrams on the label, but the correlation was weak. Standardization did not guarantee that the sample contained as much constituent as was stated on the label.

While questions have previously been raised about the unregulated dietary supplement industry, very little has been done to assess the veracity of those concerns in retail preparations. In 1995, *Consumer Reports* conducted one similar study testing ginseng, since the active constituent, ginsenoside, had been purified and was readily available as a standard.¹⁸ In testing 10 brands of ginseng, they found that “ginseng” actually represented extracts of 2 different plants, *Panax* subspecies (true ginseng) and *Eleutherococcus* or *Siberian* ginseng, which does not contain ginsenosides. Similar to the present study, they also found that while milligrams of ginseng per capsule were clearly defined on the packaging, the concentration of constituent, or ginsenoside, varied 50-fold. In our study, the concentration of constituent varied greater than 100-fold.

A study of preparations of *Echinacea* available in Germany, published in December 2000,¹⁹ revealed similar results to the present study in that some preparations had very high concentrations of constituent, and some had no detectable levels. In the German study, preparations with more species had higher contents of constituents. In our study, the more *Echinacea* species listed on the label, the less likely the preparation was to contain the labeled species, and the amount of constituent decreased with increased number of species. The level of cichoric acid measured in the study by Osowski et al¹⁹ was lower than the levels seen in our study. In the study by Osowski et al, the concentration of cichoric acid varied 10000-fold, whereas variations of only 100-fold were seen in our study.

Of the samples labeled as standardized, none that used the same constituent that we assayed met the labeled standard. There were also 6 samples that had no measurable content. The measured levels of constituent may be low for several reasons. This may be due to increased demand for a relatively limited supply of *Echinacea*. Mature or 2-year-old plants contain 10- to 100-fold higher concentrations of cichoric acid than young plants.¹⁶ With market pressures to supply more *Echinacea*, it is possible that the herb is being harvested at a younger age, producing lower levels of constituent. Another possibility is that the level of constituent may have degraded since it was packaged. Depending on the method of preparation of the *Echinacea* used in our samples, the cichoric acid may have degraded, since there was no preservative of cichoric acid in the tablet preparations.²⁰ However, the liquid samples, which contained an adequate amount of alcohol to preserve cichoric acid, had no better association of content with labeling. Echinacoside has also been observed to degrade when left in solution for long periods.¹⁴ If degradation is an issue, expiration dates should reflect the risk of degradation of content, and all samples in our study were used within the listed expiration date.

A more likely explanation, however, is that the labeled standards on the preparations were higher than the

levels expected in nature from previous published reports. In the quantitative assessment, some of the values for echinacoside were also high (Figure 2). These values exceeded by 2 to 4 times the amount of echinacoside found in *Echinacea* in nature. This raises the possibility that echinacoside obtained through selective extraction or concentration is being added to “boost” the *Echinacea* being sold.

Limitations of this study include external validity, since samples were purchased only in 1 city. Also the samples were not assessed for contamination with other substances, which is an area of concern about the use of herbal medicines.^{21,22} While TLC has distinct advantages as a qualitative assay, some may object to the use of TLC as a quantitative assay. Quantitative TLC has been shown to correlate well with high-performance liquid chromatography under similar conditions with different substances,²³ but the correlation in cichoric acid and echinacoside has not yet been evaluated. Our results were similar to those seen in the study by Osowski et al¹⁹ in the 1 brand analyzed in both studies. Osowski and colleagues found no measurable content, and we found no measurable content. The lot numbers are not similar.

In summary, we found that labeling of *Echinacea* preparations was frequently inaccurate. Only 31 (52%) of 59 preparations contained the species listed on the label. Claims of standardization by the manufacturer did not indicate that the preparation reliably contains the labeled amount or even the labeled species. While dietary supplements remain unregulated by the FDA, the US Pharmacopeia (USP) launched a pilot program in February 2001²⁴ to ask manufacturers of dietary supplements to voluntarily comply with testing of ingredient samples and to participate in postmarketing product surveillance in return for certification of quality standards by the USP. The data from this pilot program will be used to develop a national quality ingredient program for dietary supplements. The USP weight standards for *Echinacea* were used by only 5 (8%) of the samples surveyed in our study, and none of those products had content consistent with their labeling.

In addition to concerns about the appropriate labeling of *Echinacea* for sale to the public, the content of *Echinacea* used in clinical studies should be clarified to ensure better external validity of the results. In the study by Osowski et al,¹⁹ a tincture previously used in a “positive” clinical trial of *Echinacea* was found to have no measurable *Echinacea* content. That same brand of tincture was found to have no measurable content in our study. Development of standards for the measurement and comparison of species and preparations of dietary supplements would help to broaden the applicability of clinical research with those supplements.

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