

## Blackie Memorial Lecture 2001

### **Homeopathy: Progress and Promise: A Critical Perspective**

**John P. Borneman**

Mr. Nickson, Mr. Holland-Martin, members of the Blackie Foundation, distinguished colleagues, good evening. I am honored and humbled to be here this evening to offer a few remarks as part of the ongoing Blackie Memorial Lecture series.

I would like to thank my colleagues Ronald William Davey, Marianne Heger, Andy Bormeth, Jacky Abecassis, Dana Ullman, Margot Murphy Moore, and Michael Quinn for their assistance in preparation of this paper. I also gratefully acknowledge Dr. Mark Phillips and the staff at Standard Homeopathic Company for their logistical support.

One wonders though, why in fact, I have been asked to speak with you tonight. It brings to mind the working definition of an expert. An expert, it is said, is "a fellow in a fine suit who comes from out of town. He borrows your watch to tell you the time, and then pockets your watch as he quickly gets out the door". In this regard I hardly hold myself out as an expert in the field of homeopathy. I offer you these thoughts as my own opinion, and fear that as I take full responsibility for them, there may be some interesting responses from the listener.

One is also fearful expressing opinions to such a gathering of distinguished and well schooled scientists, because while my education is indeed in the sciences, I left the active practice of chemistry over 20 years ago to pursue my interest in the business of homeopathic pharmacy. I therefore fully admit that my perspective is quite practical, and from the point of commerce. One could ask, am I a 'true believer'? I cannot answer this, but I think not. I have been active in the field since I began my apprenticeship at the age of 13. My great-grandfather began his career in this field as an apprentice in the last decade of the nineteenth century; my grandfather in the first half of the 20<sup>th</sup> century and my father at the midpoint of the 20<sup>th</sup>. Perhaps my daughter will join the family profession in the 21<sup>st</sup> century. One can never tell. But homeopathic pharmacy has been the Borneman family profession for over a century. My father is quick to point out that nepotism is quite a good practice so long as all involved are actually competent. Either we are all victims of the same sort of complex genetic self-delusion, or there really is something to homeopathy. Over 30 years, one does have the time to wonder about a few things- so perhaps one could characterize me not as a believer; but as a benevolent skeptic. It is yours to decide.

And why choose an American to address you this evening? Frankly, I have no idea why! One can speculate though. I have been accused by one distinguished member of the Blackie Foundation of being an 'unreconstructed colonial'. I believe that the title was meant to be pejorative. However, I do not think so. I think it gives great perspective to the way that Americans are seen in Europe, and more importantly, may help to explain the perspective that Americans have of Europe. I offer only this- while the election of a President might be a great trauma for Americans, it points out the little truck given by most of my countrymen to convention. Americans as a people 'calls them as they

sees them' and it is in this distinctly American tradition that I offer you my remarks tonight.

So, to the 'practical' point of view of homeopathy. Where can one go to assess the progress that has been made in the field in the last 2 decades? What data are available to establish trends and give perspective? What metrics exist that allow one to form defensible conclusions about these trends? In fact, how can we answer the question, 'how are we doing?'

I have chosen to analyze trend data concerning publication of research, measures of consumer awareness, sales of homeopathic products, distribution trends of homeopathic products and relative consumption of individual homeopathic medicines as potential markers for the evolution of the field. I make no claim that with the limited metrics available, these data are conclusive. I can only offer my opinion within the context that I have already explained, or as the poet said, "easily riled, given to shout, frequently wrong; but never in doubt".

So, we return to our question. Where is homeopathy in the second month of the first year of the twenty-first century? In America, the dot-coms have crashed and only the few remain. Their metrics are based not on profits but cash burn rates. Talk of a recession has begun and has replaced inflation as the great economic bogeyman. The natural products industry (of which homeopathy is an integral part) which achieved stratospheric compound average growth rates for revenues in the 1990's along with concomitant share prices, has crashed. Share prices and market capitalizations for natural products companies are as little as 10% of their historic highs. Share values of the retailers on which the industry relies are also dramatically depressed with revenue growth in the single digits if at all, and inventory re-alignment with product returns are the order of the day. Perhaps we should conclude right here with a shared Arsenicum cocktail.

But, let's not. Let's move forward and observe more closely the homeopathic business. Metrics for the homeopathic industry are very challenging. Most companies throughout the world are closely held and do not release revenue data. Further, outside auditors such as Nielsen and Information Resources (IRI) in the United States do not report on homeopathic pharmaceuticals as a separate category; so data mining is difficult at best. Fortunately, my colleagues at Boiron in France and DHU in Germany have been helpful in providing some information that can be overlaid on scan data and proprietary industry data from the United States.

For the period 1982 to 1997, sales of homeopathic medicines in France rose 3.7 fold in a fairly linear fashion. In the United States, for the period 1987 through 1999, the sales of homeopathic drugs grew about 5.2 fold; with a substantial amount of the growth occurring in the last 5 years of the 1990's. For the conventional pharmaceutical industry, sales of non-prescription drugs increased from \$15.4 billion in 1995 to \$18.9 billion in 1999, an increase of some 22.5%. Even so, in 1999 worldwide homeopathic pharmaceuticals represented only about \$1.5 billion or 0.70% of the total pharmaceutical market of \$211 billion. In the United States, the figures are more dismal with an estimated market of only \$0.25 billion, representing less than 0.26% of the total \$88.4 billion pharmaceutical industry. One quarter of a billion dollars- \$250 million. As a comparison, Tylenol's sales in the US were in excess of \$88 million

last year in the U.S. alone- worth roughly one third of the total value of the U.S. homeopathic business. Vitamin, mineral and supplement (V/M/S) sales in the U.S. were over \$15 billion in 1999, meaning that the sales of homeopathic drugs represent only 1.5% of that market. Honestly, if we are so good at what we do, why do we represent so little share of worldwide healthcare expenditures? Is it that homeopathy is unknown?

Industry estimates (and the caution regarding metrics is reiterated) are that in France in 1998, 38% of the population used homeopathic medicines. In Germany, the percentage is 34, it is 37% in the Netherlands and approximately 20% in the U.K. In the United States, the figure published by Time Magazine is 2%. By Time's reckoning, only 5 million Americans use homeopathic medicine. But, we know that by sales tracking alone, the actual use figure is more in the order of magnitude of 27 million people or 12% of the population. Why is there the disparity? In fact, the preponderance of consumers who buy a homeopathic medicine (typically a combination product) at a chain drug store, grocery store or mass merchandiser do not actually know that they have purchased a homeopathic medicine. They are aware that the product is 'natural', that it has no side effects and, judging by repeat sales, that it has been effective. Curiously, while market surveys indicate that upwards of 96% of American consumers actually read OTC labels (the figure is 97% in the UK) , it appears that most Americans have not taken the time to read the label and package insert to sufficiently understand that the medicine they have used is a homeopathic medicine. The obvious sequelae of this syndrome are that American consumers do not avail themselves of other homeopathic medicines- and market growth for homeopathic products is limited by definition. Brand awareness for homeopathic medicines is building in the United States, but current data show that awareness of homeopathic medicines is growing at a much slower rate than it is for other consumer products- owing principally to the small ad spends for homeopathic medicines. Small industries beget small add budgets beget low consumer awareness. The result is an excruciatingly slow growth strategy- and in some ways a culture of poverty, "we have not the resources, so we cannot grow". One wonders if the payoff for laboring in the homeopathic vineyard is anonymity. And, the problem of homeopathic anonymity is not limited to the United States. If the largest figure for use of homeopathic medicines is 38% of the population in France, what does this say for the acceptance of a medical theory that is over 200 years old? Does consumer awareness correlate with effectiveness of the medicines?

It would be worthwhile at this point to take a brief look at media coverage for homeopathy in the United States. For the period April 1993 through February 1997, the National Center for Homeopathy, a public interest group representing consumers of homeopathic medicines, tracked the number of stories that appeared in the mass media on the topic of homeopathy. The NCH criterion was that homeopathy should be a key focus of the story and not a mere mention. NCH staff ranked the story as positive negative or neutral.

For the period, 835 stories appeared in the mass press. Of those stories that the NCH rated, 331 or 39.6% were considered neutral, 87 or 10.5% of stories were considered negative and 391 or 46.8% of stories were rated positive. For the measured period, 26 or 3.1% stories were not rated. The number of stories appearing in the press peaked in late 1994 in the 50 per month range, slowly declining to an equilibrium level of 15-20 stories per month by late 1997. NCH reports that this trend continues. Similarly

interesting is the tone of the media reports. For the period of April 1993 until the peak in late 1994, the tone of stories was decidedly positive, becoming more neutral in late 1994 and following years. Negative studies remained in a range near their average value of 11% each month. One observation that can be made is that in 1993 and 1994, the media discovered homeopathy. The reporting reflected a decidedly positive- potentially "romantic" view. As time drew on from late 1994 and beyond, stories became more neutral or balanced- and declined in number- reflecting perhaps the decline in news value of homeopathy, the story was no longer hot. Of course, the NCH evaluators were subject to their own biases that certainly could have confounded the data. But these limitations understood, the pattern of discovery, romance and acceptance certainly appears in these data. Even so, the overall number of stories is fairly modest compared to the total news output in the U.S. in any given month.

Consumer confusion certainly enters into this picture. More and more, it appears that average consumers of homeopathic medicines cannot distinguish the difference among homeopathic medicines and their herbal cousins. While this distinction may not appear significant on the face, it is of particular importance in the U.S. where homeopathic medicines are regulated and treated as drugs while herbal products, vitamins and supplements are regulated as the equivalent of foods.

Clearly this state of affairs cannot be explained solely on the basis of advertising expenditures alone. What other structural factors contribute? If a consumer has a clinical success with a homeopathic medicine, for example, their flu symptoms have been relieved or their teething baby quieted, the consumer may wish to seek further homeopathic care. They will need a physician. In France, the consumer will have 18,000 physicians from which to choose. In the Netherlands, 4,700 physicians, in the UK 1,500 and in the US fewer than 2,000. These small populations of providers get much larger when one includes Heilpraktitioners in Germany, or Chiropractors and Naturopaths in the US. An even larger area of undercounted providers are the conventional physicians who do not practice homeopathic medicine as their primary discipline; but rather include a homeopathic drug or two into their allopathic practice. These physicians include pediatricians who may use Belladonna or Chamomilla, Orthopedists who may use Arnica, or Cosmetic Surgeons who may use Calendula. *{Our business is in LA and the number of cosmetic surgeons- per capita more surgeons than police- is growing nicely}*

Additionally, the discussion of the provider channel raises the whole issue of the unlicensed practice of homeopathic medicine. In the UK, where there is a common law tradition of the unregulated practice of medicine, there is an existing body of non-medically trained homeopathic practitioners. In the US, this movement toward non-medically qualified practitioners is growing; but, it is stymied by highly restrictive practice laws limiting the use of homeopathic drugs to licensed physicians. I make no comment on the wisdom of changing these laws, save the observation that insufficient study has been done on the relative merits of the practice of homeopathy by non-medically trained practitioners being included, or conversely excluded, from the conventional medical model. Which is best? Are there any data? How important is it for homeopathy to opt into the existing medical infrastructure in any given country? Does homeopathy benefit more by being included in- or excluded from, the world medical delivery system?

One conclusion that can be drawn from the existent data is that if a consumer has a clinical success with a homeopathic medicine and makes a decision to seek further professional treatment; the probability is that the consumer will not find a medically qualified and licensed physician to treat them with homeopathic medicines. As a result, the cascade of events begun by the homeopathic manufacturer to introduce the consumer to a clinically successful experience with a homeopathic medicine is abruptly halted when the consumer cannot fulfill their demand for a homeopathic doctor. This phenomenon does not cause a shift in the demand curve for homeopathic medicines, it causes the termination of the curve. The small and static number of homeopathic providers is an important limitation in the popularization and eventual economic success of homeopathy.

How does the structure of the medical delivery system affect the economic model for the pharmaceutical business? More clearly stated, how does the practitioner or professional market for homeopathic medicines affect the consumer channel?

Homeopathic medicines can be divided into two basic types: single entity homeopathic medicines that are typically used by physicians and more educated consumers, and combination medicines most usually sold as consumer products. In France, Spain, and the UK; the proportion of single entity products to combination medicines is in the order of magnitude of 75:25. In the Netherlands and Germany, the ratio is precisely the opposite- in the order of magnitude of 30:70. In the United States, the ratio is more evenly split at 55:45. The obvious question from these data is can one build a growing market in France and the UK in an environment where three fourths of the business is from a static group of practitioners? In Germany and Holland, the market is quite different as it is more consumer driven. In the U.S., the model shifts each year away from single entity products and to consumer products. Growth rates in each market reflect this shift. Markets where combination consumer products are the dominant form of delivery have typically higher compound average growth rates for revenue. Those markets in which single entity products are dominant have lower rates of growth. There are of course, additional influences- the most important of which is government reimbursement. In France, it is likely that the government will pay for the homeopathic medicine. In the U.S. the government pays for nothing. Thus, the question remains- should homeopathy integrate into the conventional model? How can the number of homeopathic practitioners be increased in order to service the increasing demand from consumers?. Growth in the practitioner segment and training of these same practitioners is a core issue for homeopathy in this century.

It may be of some interest to review data sets from several U.S. homeopathic pharmaceutical companies who engage in the sale of homeopathic single medicines to different target consumers. Some cautions are advised from the outset. First, these data all originate in the United States and may reflect cultural biases relating to the prescription and use of such drugs as compared with similar firms in Europe or elsewhere. Second, specific business models, or shifts in a business model during the reporting period, can have a substantial impact on the data reported, one can see this clearly in these data. Third, due to data capture limitations, the time periods over which data were collected varied. And, fourth, the data are self-reported and not audited by any third party, thus the accuracy of the data is dependent on the reporting party. These

provisos having been stated, the patterns of the data share some consistency and certain observations can be made.

Data were collected from three companies that have substantially different go to market strategies. Company "A" has a business model which targets single medicine sales directly to practitioners who specialize in using what is called the classical homeopathic model. These practitioners use single medicine, single dose techniques and are interested in the constitution of the patient as much as acute symptoms. Company "B" has oriented its business to selling homeopathic medicines through retail channels- independent natural food stores and independent pharmacies in the U.S. This business model is oriented to consumer products and medicines which will be self-serve (or as near to self-serve as possible) in the retail environment. Company "C" has developed a model for selling homeopathic single medicines directly to consumers through catalogues and over the internet. This model is called "direct to consumer" and allows for much greater information to be conveyed to a consumer about a particular product than the retail channel strategy of Company "B".

Clearly, these business models produce distinctly different cohorts of data showing consumption of homeopathic single medicines. However, some patterns and similarities in the parameters can be observed. The first parameter is the total number of single entities sold in a given period- that is the total array of homeopathic single medicines that were sold by each company. Second, is the concentration of business, that is - the percentage of units sold as a percentage of the overall entities offered from the company (the 80:20 rule). The third area of interest is the list of the top ten selling medicines purchased in each business model. A fourth parameter to observe is the way in which some medicines increase or decrease in popularity throughout the period of reporting. Of course, the evolution of the data over the reporting period is also worthy of a few comments.

For Company "A", data were taken at 2 year intervals for the period 1990 to 2000.

<u>Year</u>	<u>"A" 1990 %</u>	<u>"A" 1992 %</u>	<u>"A" 1994 %</u>
75% of units	42 10.27%	47 11.35%	48 10.76%
80%	55 13.45%	60 14.49%	62 13.90%
85%	76 18.58%	83 20.05%	83 18.61%
90%	104 25.43%	114 27.54%	115 25.78%
95%	154 37.65%	167 40.34%	175 39.24%
Tot Drugs used	409	414	446

<u>Year</u>	<u>"A" 1996 %</u>	<u>"A" 1998 %</u>	<u>"A" 2000 %</u>
75% of units	65 12.13%	92 15.59%	98 17.01%
80%	84 15.67%	117 19.83%	125 21.70%
85%	112 20.90%	151 25.59%	164 28.47%
90%	151 28.17%	200 33.90%	219 38.02%
95%	221 41.23%	285 48.31%	308 53.47%
Tot Drugs	536	590	576

used

Reviewing these data, a number of observations can be made. The total array of single medicines sold increased from 409 to 576 over the eleven-year period, increasing in a fairly linear fashion with the exception of a small decline in the last year. One should bear in mind that the total number of approved drugs in the United States is 1286. Thus, although sales from this company were targeted directly to classical physicians, these physicians utilize less than 1/2 of the official drugs available to them.

For company "A" during this period, the concentration of sales also evolved. One can see that in the first year reported, 1990, 75% of the units sold by the company were in 42 drugs, or slightly more than 10% of the total drugs offered. The business concentration was stable through 1996 when it began to shift. In 1998, 75% of business concentration was in 92 drugs or 15.59% of drugs offered and in the year 2000, the business shifted to 98 drugs or 17.01% of offerings. The concentrations at 80% through 95% showed a similar pattern. In 1990, the 95% business concentration was in 154 drugs or 37.65% of the entities offered. By 2000, the 95% interval was in 308 drugs or 53.47% of the offerings. While this evolution shows an increase in percentage of the company's offerings that contributed to the bulk of its business (from 37.65% to 53.47%) still, customers made use of only slightly more than 1/2 of the medicines offered by the company and just 24% of those drugs official in the United States. Physicians used a wider array of medicines over the period- but still did not avail themselves of the great bulk of possible drugs that are in the Pharmacopoeia.

Company "B" uses a business model that sells single medicines through retail channels such as independent pharmacies and natural food stores.

<u>Year</u>	<u>"B" 1994</u>	<u>%</u>	<u>"B" 2000</u>	<u>%</u>
75% of units	33	3.67%	19	2.91%
80%	42	4.67%	22	3.37%
85%	57	6.33%	27	4.14%
90%	87	9.67%	37	5.67%
95%	152	16.89%	70	10.74%
Tot Drugs used	900		652	

For the seven year period 1994-2000, Company "B" reduced the total number of drugs it offered from 900 to 652. The 75% level of business concentration shifted from 33 drugs, or 3.67% of total drugs offered in 1994 to 19 drugs, or 2.91% of total drugs offered, in the year 2000. This contrasts dramatically with company "A", whose drug offerings increased as its business concentration decreased in the same period. A similar effect at the 95% business concentration level for company "B" can be observed for the period 1994 through 2000- from 152 drugs, or 16.89% of drugs offered, to 70 drugs or 10.74%. Company "B" effectively cut its offerings by 1/3, while concentrating its business in 1/2 the number of drugs that it sold seven years previously (from 172 to 70). Sales for the period are reported to have increased in total units sold. In short, the customers of Company "B" not only increased their purchases, they concentrated their purchasing in one half the number of drugs that they had utilized in 1994.

Company "C" uses a business model that offers homeopathic single medicines directly to non-practitioner consumers through mail order catalogue and internet sales.

	<u>"C" 1997</u>	<u>%</u>	<u>"C" 2000</u>	<u>%</u>
75% of units	31	12.50%	27	16.56%
80%	37	14.92%	33	20.25%
85%	43	17.34%	39	23.93%
90%	54	21.77%	49	30.06%
95%	77	31.05%	63	38.65%
Tot Drugs used	248		163	

As can be observed, Company "C" offers far fewer single entity drugs than either Company "A" or Company "B". In the four year reporting period reported, the number of entities offered by Company "C" declined from 248 to 163 in a pattern similar to Company "B" and contrary to the data seen for Company "A". Business concentration at the 95% level of units sold for Company "C" shifted from 77 in 1997 to 63 in 2000. Interestingly, the percentage of single medicine offerings purchased at the 95% level of business concentration climbed from 31.05% to 38.65% because the total array of single medicines offered was reduced. Again, sales by this company were indicated to have increased. By 2000, Company "C" offered only slightly more than 12% of the official medicines monographed in the Homeopathic Pharmacopoeia of the United States to its customers and 95% of its business was concentrated in slightly more than 5% of official drugs.

Another interesting parameter that can be observed is the top ten selling medicines for the reporting companies during the period in question.

Top 10 drugs	<u>"A" 1990</u>	<u>"A" 1992</u>	<u>"A" 1994</u>	<u>"A" 1996</u>	<u>"A" 1998</u>	<u>"A" 2000</u>
1	SULPH	SULPH	SULPH	SULPH	LYC	LYC
2	PULS	CALC	NAT M	CALC	SULPH	CALC
3	CALC	NAT M	CALC	NAT M	MED	SULPH
4	NAT M	PULS	PULS	LYC	NAT M	CARC
5	LYC	MED	LYC	MED	CARC	MED
6	NUX V	SEP	MED	PULS	PULS	SEP
7	PHOS	LYC	SEP	PHOS	CALC	PHOS
8	SEP	NUX V	ARS	STAPH	SEP	NAT M
9	ARS	SIL	NUX V	SEP	PHOS	SIL
10	MED	PHOS	STAPH	NUX V	NUX V	PULS

Top 10 drugs	<u>"B" 1994</u>	<u>"B" 2000</u>	<u>"C"1997</u>	<u>"C" 2000</u>
1	ARNM	ARNM	ARNM	ARNM
2	RHTX	NUXV	FEPH	MAGP
3	NUXV	RHTX	MAGP	KALP
4	PULS	CHAM	RHUST	RHUST
5	CHAM	PULS	KALIP	FERP
6	BELL	BELL	SILICA	NATP
7	SULP	SULP	NATP	SILIC
8	IGNA	HYP	NATM	CHAM
9	ACON	IGNA	CHAM	CALP
10	ARSA	ACON	CALP	NATM

As can be observed, Sulphur and Lycopodium are the most commonly purchased medicines by the customers of Company "A" during the period. For Companies "B" and "C", Arnica is the most commonly purchased drug, followed by Rhus Tox and Nux Vomica for Company "B" and Ferrum Phos, Magnesia Phos., and Kali Phos. for Company "C". These drug choices are very reflective of the populations served and their prescribing habits. What is more interesting is the stability in the top selling drugs over the course of a decade. However, certain medicines can rise or fall in popularity.

<u>Drug</u>	<u>"A"</u> <u>1990</u>	<u>"A"</u> <u>1992</u>	<u>"A" 1994</u>	<u>"A" 1996</u>	<u>"A" 1998</u>	<u>"A" 2000</u>
Carcinosin	55	39	19	15	5	4
Antimonium Crud..	58	55	60	63	64	119

<u>Drug</u>	<u>"B"</u> <u>1994</u>	<u>"B"</u> <u>2000</u>	<u>"C"1997</u>	<u>"C" 2000</u>
Carcinosin	97	0	0	0
Antimonium Crud..	71	78	0	0

Carcinosin, which is a homeopathic drug of challenging pedigree, and for which data on proving material is controversial, was the number 55 rank drug for Company "A" in 1990. It rose steadily in popularity for the following eleven years, ending with a number 4 ranking in fiscal 2000. For Company "B", Carcinosin fell from 97 to zero as it was most likely discontinued due to non-compendial status. It was never sold by Company "C". Antimonium Crudum, on the other hand fell in popularity from a 58<sup>th</sup> rank in 1990 to 119<sup>th</sup> rank in 2000 at Company "A", while maintaining its rank at Company "B"- in an environment where drug offerings were being limited. Again, Company "C" never sold the medicine.

Other medicines have similar curves. For example, Dolphin's milk (Lac Delph), a hitherto unknown homeopathic medicine gained in popularity at Company "A" from the 447<sup>th</sup> position in 1994 when it was introduced, to the 77<sup>th</sup> position in 2000. This is most likely due to education of physicians about the drug and increasing experience with its use.

While complete analyses of these data may yield numerous interesting observations, simple trends tend to indicate that while there is variability in the number of single medicines used by different consumers - physicians, or non-professionals-, absent some variations in ranking, the choices of single medicines purchased are stable by channel. Further, only a very small percentage of official medicines are actually sold. That is to say, American consumers are not taking advantage of much more than 1/3 of the total array of approved and registered single entity homeopathic drugs in the United States. Is this due to education or to efficacy?

Homeopathic combination and consumer products offer a similar picture. An analysis of the natural foods distribution channel in the U.S. is worthy of consideration. This channel is comprised principally of independent retailers who carry a wide array of homeopathic medicines. These stores cater to an educated consumer and are typically staffed by well-trained,

although non-medical, personnel. This channel is effectively unregulated, offering a full line of non-prescription (OTC) and consumer products.

In calendar year 1999, there were 1060 separate homeopathic medicines (sku's) offered for sale through the natural foods channel of distribution in the United States. The natural foods class is important, because it represents upwards of 40% of total sales of homeopathic medicines in the United States in this period. Data analysis is very interesting. In these data, 50% of revenue was produced by 63 sku's (5.9%). A total of 75% of revenue came from 194 sku's (18.3%); 80% of revenue was produced from 244 sku's (23.0%), 90% of revenue from 393 sku's (37.1%) and 95% of revenue was earned from 523 sku's (49.3%). Stated another way, 50% of sales were in 6% of products offered and fully one half of the products offered for sale through the natural foods channel for 1999 produced less than 5% of the total revenue for the channel. Why? One could, of course, blame the old bogeyman of advertising. Another argument could be made that merchandising techniques in the channel were unsophisticated. And, in fact, an argument can be made that some of these homeopathic products are orphan drugs with highly specialized uses and concomitantly small sales.

But, I believe the problem goes much deeper. I would like to assert, that for at least a portion of these products that don't sell, some of them may not actually be clinically effective. Many of these consumer products are formulated with little thought given to basic homeopathic principles and are comprised of single homeopathic medicines about which little is known. Many of these products are sold without any clinical investigation or a shred of actual evidence that the products are effective. Many products are formulated using bizarre medical theories that use homeopathic medicines as the intervening element; but that have little to do with the Principle of Similars or the microdose. Many companies simply use the regulation of homeopathic medicine as a cheap license to sell whatever they wish. Fortunately, consumer data are clear. Natural Food Store consumers consistently purchase a group of about 250 or more consumer products of the 1060 offered, while the remainder do not sell. And yet, the natural foods consumer channel is critically important for the growth of homeopathy in general.

Thus, we have an emerging market on which pressure is put from two sides- a lack of licensed care providers and the apparent sales of questionable products by some manufacturers.

Another way to come at this problem is to ask, is there a correlation between repeat sales of homeopathic medicines and efficacy? There are no published data to support such a correlation. But, logically one could assume that consumers are unlikely to continue purchasing products that do not work. Making this admitted assumption- that there is a positive correlation between product effectiveness and repeat purchases- studying trial and repeat rate data could help one formulate an answer to the question "do homeopathic medicines work?"

In the United States some mass merchandisers have sophisticated point of sales data capture that allow a manufacturer to determine not only which individual store sold each piece of product; but at what date and time. These data are analyzed by manufacturers to create and analyze product promotions and to adjust inventory. These data are also useful in giving a glimpse at trial rates and repeat rates. Interestingly, in one large

mass merchandiser in the United States, data for the 12 month period trailing 12/31/00 are very consistent. For Product #1, 59.30% of individual stores of the over 2500 total sold 80% of the product. . For Product #2, 55.45% of the individual stores sold 80% of the product. For Product #3, the figure was 55.62% and for Product#4, the percentage was 46.67. One conclusion that can be drawn from this concentration of business is the trial rates for the medicines were low and the repeat rates were high. These data are further supported by measuring customer purchase frequency. For these products, it appears that the consumer is indicating by repeat purchase behavior that the homeopathic product actually works. So another element is added to the mix- how can the awareness of homeopathy be raised in such a way that trial rates for use of homeopathic consumer products are also raised?

Is it time for more regulation? The European regulatory system for homeopathic pharmaceutical products features a two tier approach with both national and pan-European components. The most typical systems divide homeopathic drugs into two categories- those which make claims and those that do not. For drugs not making claims, the registration process is reasonably non-restrictive and straightforward, with some national variants. Of course marketing a product without claims is a formidable task. For those products that wish to make claims, the regulatory schema has more national variants. While the European Directives allow for a simplified registration process, countries still can and some do require some proof of efficacy. A notable exception is Germany where regulators may opt to accept "scientific documents" including provings and clinical data.

In the United States, by virtue of the recognition of the Homeopathic Pharmacopoeia of the United States (HPCUS) in the Federal Food, Drug and Cosmetic Act, homeopathic medicines are classified as drugs under federal law. This means that from the perspective of the regulation of their manufacturing, marketing and sales, homeopathic medicines are treated virtually identically to their allopathic counterparts. All homeopathic drugs are required to make claims. However, there is a major difference in the regulatory treatment of homeopathic drug products in pre-market approval. In lieu of the conventional clinical trials and pre-market approval process that is required of allopathic medicines, homeopathic drugs fall under the auspices of the Homeopathic Pharmacopoeia approval process which requires only a drug proving and evidence of clinical effectiveness.

This alternative regulatory treatment is simultaneously a blessing and a curse. While this methodology recognizes that homeopathic medicines are distinctive from allopathic drugs, enormous pressure is placed on the Homeopathic Pharmacopoeia. The HPCUS places significant import on the Principle of Similars and the clinical use of the drug according to the similimum. Even so, there is constant pressure to approve drugs that are solely intended for use in the microdose without any relationship to the Principle of Similars. While the HPCUS resists such pressure, it is a constant stress, and since HPCUS has no control over the regulation or the use of homeopathic medicines after the individual monograph has been approved, manufacturers are free to torture the regulatory structure as they see fit. Since FDA in the United States, like many regulatory agencies, is under-funded; and since the public safety impact of enforcement of homeopathic regulations is seen to be low- there are no bodies in the streets- FDA frequently does not enforce its own

regulations, let alone those of the HPCUS. The results are that the US market has become the victim of numerous so-called homeopathic medicines which receive big ad dollars; but no clinical testing. In the U.S., the situation falls to industry to self-regulate. While I am proud of many of my colleagues and the decisions that they have made in this regard, it is clear that there is much to be done, including perhaps the necessity for clinical evidence of effectiveness before a new product goes to market.

This comment will probably not win me a popularity prize with some in the business of homeopathic pharmacy. But, my guess is that many on the industry side feel as I do. Manufacturers have an obligation to customers to provide products that work. One should understand that as a jury, customers are rarely wrong. Repeat sales will come to clinically effective products. Those products that do not work do not sell. Most importantly, consumer sales and response data simply do not lie. Half the homeopathic products intended for the natural foods channel in the United States produce no revenue. So, we have much to do.

It would be difficult to make a complete assessment of the state of homeopathy without making a few comments on research. Making such comments worry me for several reasons. First, we have heard many excellent presentations today on the topic of research in homeopathy from presenters who are far more expert in the field than I am. I fear that by this time of the evening we may all need a bit of a respite from the topic of research. So I offer the following thoughts not as a self-declared expert on the topic of research in homeopathy; but more as one interested in the implications and impact of such research. We face some fairly clear questions in this topic. For whom do we do research? What is our motivation? What is the quality of the work product of the research projects?

An informal bibliographic review produces some informative data. For the period 1943 through 1997 there were some 244 studies that were reported in some way. Not all were published; and of those published, not all were peer reviewed. Of course, Linde and colleagues have done excellent work in assessing the quality of research and I shall leave that area to him.

Looking at reports of research by decade, there was one study reported in the 1940's, and none in the 1950's. Five studies were reported in the 1960's, 24 studies were reported in the 1970's and 101 studies reported in the 1980's. For the period 1990-1997, there were 113 studies reported. These data show a fourfold increase from the 1970's to 1980's and a 15% plus increase from the 80's to the 90's. These data seem to reflect reality quite nicely- after all, the biennial international meetings of the Royal London Homeopathic Hospital dedicated to the topic of research were first organized in 1997, and interest appears to be on the rise.

Sources of the reported studies is also not surprising, for the period 1943 through 1997, of the 244 reported studies, the following were the countries of origin:

Germany	57	
France		51
United Kingdom	46	
United States		33
Italy	16	
Elsewhere	41	

These data are unremarkable. The less encouraging observation is the manner in which the studies were made public: Homeopathic Journals published 67 studies. Conventional Journals published 58 studies. Complementary and Alternative Medicine Journals published 37 pieces; while Meetings and Proceedings from meetings featured 31 studies. Twenty-six trials were not published and 25 appeared as unpublished academic papers or theses.

This returns one to the basic questions about the impact of research. What is the purpose of this work? Is it for the use of the practicing homeopath or to convince the skeptical party? How long do we need to dwell on proving homeopathy before we focus on improving homeopathy? Has anything new been discovered? Have the techniques of homeopathy been improved? Has research on homeopathic topics reached a level that offers new information to the user of homeopathic medicine that is developed and presented in a way that will be respected by the entire medical community? Linde and colleagues have observed that there is increasing evidence that more rigorous trials tend to yield less optimistic results than trials with less precautions against bias. Is this because the homeopathic effect is so subtle? Or, are our fundamental pre-conceptions about homeopathy being challenged? Linde goes on to note that in a controversial area like complementary and alternative medicine, in which many trials are performed by proponents with little research experience and published in non-peer-reviewed journals, one might expect that this problem could be even more pronounced. Perhaps a dose of healthy skepticism is the salubrious tonic for homeopathy.

Of course, there are many mitigating issues related to research on homeopathic topics. Publication bias is mentioned by many researchers engaged in the field as a major impediment to having their work appear in peer-reviewed journals. As training of investigators improves, so does research quality, and one would hope that the publication rate would increase. In my opinion, the major stumbling block is neither bias nor money. It is focus. A clear consensus research agenda is required so that studies are reproduced and new topics tackled efficiently and effectively.

One could assert that there is a parallel between the results from the current choices of research topics in homeopathy and the phenomenon observed in sales of combination homeopathic medicines. I have observed that the 'old time' combinations seem to sell better than most new combination product releases. Perhaps this phenomenon is due to the fact that in the past formulators relied on clinical fundamentals, using big acting remedies that were targeted for broad results. Newer combinations seem to use smaller acting drugs that aim at more subtle or narrow effects. The same may be true with research topics, perhaps more focus should be given to large effects, with emphasis on those studies that can be most easily reproduced. Commercially oriented research projects should not be discouraged. Product related research should not be seen as counter to the overall goal, but integral to it. Success breeds funding. Funding ensures success. There is much to be done.

So, this evening, what can we say about the way forward? Since you were kind enough to ask my opinion, I will offer it with all of the aforementioned provisos- remember, frequently wrong, but never in doubt!

First, I think that we should change the "language" of homeopathy: from remedy to medicine, from belief to understanding - as we become benevolent skeptics. We must communicate among ourselves and with the world in a lingua franca. It is of great importance that we disentangle a belief-based system of homeopathy in favor of a system based on results. I am not saying that we should not believe in our work, I am saying that our work should not be based on belief. A healthy dose of skepticism could benefit us all.

Second, it is important to train more medically qualified homeopathic practitioners. While a primary objective of planners for homeopathy should be the delivery of health care utilizing homeopathy in general, it is of utmost importance that homeopathic medicine be integrated into existing health care delivery systems throughout the world. This integration will involve clear communication with all others (friendly or not) who have an interest in healing while at the same time training physicians of all types to use homeopathic medicines to their maximum advantage. Emphasis needs to be placed on the economics of homeopathic practice, including insurance and reimbursement to assure that physicians can actually earn a living in homeopathic practice. It is clearly ironic that a consumer base for homeopathic medicines has been built over the last 30 years throughout the world, and a physician base has not

Third, we should improve the clinical understanding of existing homeopathic drugs and eliminate those that do not work. This may sound harsh; but it is no worse than pruning a rose. If energy can be committed to the full understanding and utilization of existing homeopathic drugs, the practice of homeopathy can flourish. Again, data do not lie. There are many official homeopathic medicines that simply are never used. Either they are not well understood, or they do not work. Not every substance can be a homeopathic medicine. Effort is required in this area.

Fourth, we should seek new drugs that have strong clinical data. As curious physicians research and push to the edge of what is known about homeopathy, new drugs are being introduced. Many of these new entities are not supported with strong science. One should balance curiosity with skepticism to the benefit of all. A culture of the 'remedy of the month' should be avoided, it distracts serious practitioners and interferes with serious study.

Fifth, the non-medically qualified practitioner debate should be resolved. This is particularly true in the United States. Resolution of this issue cannot be easy. The debate exists at the interface of belief, ego, philosophy, education, regulation and money. It has as its context the question of whether homeopathy should or should not be integrated into the conventional medical model. However, as long as the issue remains open and unresolved, the community of those people interested in homeopathy will remain without focus- and unable to move forward.

Sixth, the community of homeopaths and homeopathic manufacturers should co-operate with regulators in establishing standards for consumer products. Self-regulation has only worked to a point. The Principle of the Similars needs to be re-enforced as the basis on which homeopathy exists and the bedrock of its medicines. This effort will not be without risk, but carefully done, a new regulatory framework could be very powerful.

Seventh, homeopathy should integrate into the medical system. There is a dynamic tension between the need to maintain the identity and uniqueness of homeopathy and the desire to make homeopathy accessible to the world's population. If we rid ourselves of our insecurities by knowing clearly that which homeopathy can accomplish, and that which it cannot, the community of homeopaths throughout the world can have the confidence to become part of the world medical system. If that which homeopathy brings to the conversation is valuable- and more importantly, is able to be proven- the best practices of homeopathy will be embraced. Which brings one to,

Eighth, establish a research agenda, fund it and stick to it. Research projects should be undertaken that allow for the exploration of that which we suspect homeopathy is capable and the verification of what we hypothesize to be true about homeopathy as it currently exists. The focus should not be on the general 'homeopathy works', but on the specific 'this is how a specific homeopathic entity can be utilized in world healthcare'. Research must be focused on that which can be learned about the discipline and that which can be used successfully by others. It is time to be secure enough to end our psychological need to validate ourselves to others.

And so I thank you for your kindness and your attention. These critical perspectives are offered positively and from the vantage of a life's work in the field of homeopathy. They are offered from a position of respect and admiration of those whose work has paved the way for us. Let us heal ourselves as we heal others; and understand the progress that we have made, and the promise of what we can be.

Good evening.

John P. Borneman  
22 February 2001