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Anecdotal Testing: Bad or Good?

An inside look at the claims made in the cosmetic industry and how to deal with them.

BY **DANNE MONTAGUE-KING**

I know for a fact that any of my readers who are either distributors of product ranges, or sales representatives have been faced with the following comments at least once in their careers:

"Are your products clinically tested?"
"Do you have scientifically published back up to prove your products work?"
"Exactly HOW do your products get the results you are claiming?"

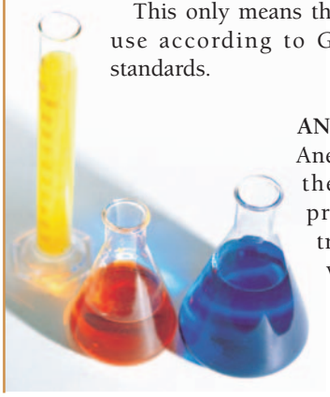
As irritating as these questions may sometimes be, there are answers you can give that will shut the skeptics up and raise your level of credibility. But before you attempt any clever answers, let's look behind the scenes of the actual cosmetic chemistry industry and see the real facts.

Anecdotal Testing vs. Lab testing

Products tested in the lab do not reveal much in regards to how they actually work on the human body. Lab testing is mainly for MSDS material (Safety Data Sheets held by the manufacturer). Micro bacterial counts, spoilage factors, toxicity, shelf life, skin irritation potentials, flammable potentials, viscosity, specific gravity and pH of the product are all done in the lab. In addition, samples from each batch are kept aside and labeled for future shelf life stability testing. Although these are important tests, none of them can tell you whether a product is physiologically viable when used by a client. In other words, these tests do not tell you whether a product will provide favorable results.

Yet many manufacturers will use a *clean* lab report in their promotional materials for their sales reps, using phrases like "TESTED BY INDEPENDENT LABORATORIES!"

This only means that the product is safe to use according to Government and local standards.



ANECDOTAL TESTING:

Anecdotal testing is merely the observation of how products and their treatment protocol work when applied to the skin. Let's say that a certain herbal lotion is applied to the skin over a long period of time and on many clients. The therapists using the lotion observe that the skin appears brighter and smoother progressively. The herbs used in the lotion may have been known centuries ago to ancient healers to possess certain qualities that help skin disorders. Word of mouth and advertisements about all of this "knowledge" spread over the years and everybody knows in general what this lotion or specific herb or ingredients do. It becomes a dependable staple of Beauty Therapy and is usually given a name such as "tonic" or "toner" or "skin firmer". There is usually no real clinical testing behind this lotion published in the Lancet or other scientific journal, yet everyone knows it works and uses it accordingly. This is a form of anecdotal testing and in my opinion is far superior and more dependable than so-called "lab testing" as far as the performance of a product goes.

The problem here is that few people know exactly how they work at the cell level in the skin. In truth, this may be good because when specific actions can be identified as having an effect at the cell level, many times the pharmaceutical companies will step in and try to control the use of that herb or ingredient.

And here lies the problem as to why we are stuck with anecdotal only testing and claims. As long as the beauty therapy business uses ingredients that are not really "proven" by intense in-vivo and in-vitro testing along with double blind clinical studies and lab analysis, there is little chance that anyone will make any major claims that could cause trouble. Therefore these products will remain under the "cosmetic" banner.

This is beginning to change rapidly and there will be new regulations regarding who can use what type of ingredient very soon. Already my outspoken cautions of the daily use of glycolic and other alpha hydroxy acids contained in several of my articles over the years have proven to be true in the eyes of the scientific community in Europe and Australia. My cautions were based on anecdotal observation and my understanding of the mechanics of how these acids work. I suffered enormous attack from big cosmetic manufacturers who were putting glycolic acid in practically every kind of product outside of deodorants (and that was probably next!). Keep in mind that many of these companies had "clinical tests" that showed their products worked. The problem lies in the fact that they designed their own claim substantiation testing.

POPULAR TERMS ALLOWED TO BE USED AND WHAT THEY REALLY MEAN:

Because our industry must refrain from using terms that make definite claims as far as actually *changing* a skin disorder or condition (according to the French Government and the USA only drugs can claim this), we have learned to fall back upon some ambiguous buzz words that seem to really mean nothing. Here is the inside story on a few that you can use.

CHEMICAL ACTION ON THE SKIN	BEAUTY THERAPY TERM
Roborant: Strengthens skin tissue by maintaining the Langerhans cells, (immune system of the skin) and the capillary walls. Niacin, Nicotinic acid Beta Glucan extracts are as few of the many roborants available.	**TONIC**
Rubefacient: Stimulates the capillaries as a vasio-diallator thus rushing more oxygen to the site of skin cells. Skin can become very pink and glowing. Cassia, certain enzymes and Horsetail are a few of many rubefacients available.	**TONER**
Epidermal Growth Factor (EFG): Not a single ingredient, as popularly assumed, but any ingredient or protocol that helps new cells proliferate at their normal rhythm to the surface of the skin. This would include fibroblast activity for new collagen. Receptor specific co-enzymes such as Vitamin A and B, Ascorbic Acid (vit.C) Essential Amino Acids, Peptides, phosphates and specific proteins are but a few of the EGF's.	**FIRMER**
Sedare Properties: Ingredients that act as a topical anesthetic on the skin. Nerve receptors are put to sleep (ganglia) temporarily, relieving stress signals to the skin that have been aroused by trauma (too much roborant and rubefacient!). Procaine, aloe, camomile and Shea Butter are a few ingredients that possess Sedare properties.	**CALMING AGENT-or SOOTHING AGENT**

These attacks did not hurt me personally, but it created a lot of headaches (and heartaches) amongst my international team members who believed in my observations about these little hygroscopic acids. You can imagine my relief and satisfaction when news of new rules on the uses of AHA's were now being considered based on the evidence that improper use of AHA's ultimately does more damage than good.

The only downside of this is that the baby may be thrown out with the bath water and therapist may be confronted with "medical use only" regarding AHA's and other keratolytics. There should be a "specific use and specific formulation" regulation for Doctors and therapists, allowing everybody to benefit from a good tool (if used properly).

My main point here is; *Do not be afraid to say your product range is anecdotally tested,* after all, everybody now knows that aspirin is much more than just a pain reliever. Doctors recommend it for heart patients and to guard against stroke. We chemists know it is the salycin, a natural chemical extracted from willow bark that is the active ingredient. But nobody knows exactly how and why aspirin really works. For years we knew *anecdotally* what it did and more recently, a little bit about how it acts in the body, but we still do not really now the entire mechanism. You can gracefully say the same things about your products if you know that they work but do not know exactly how they work at the cell level. In fact even if you did now the chemical mechanics most people wouldn't be able to understand it.

Although different words are used to describe the same chemistry, these are common to both chemists and therapists. As a distributor or sales rep, think how much more credible you would sound if you described your product using official (but allowable) terms as in the left hand column?

Manufacturer's Gimmicks to Avoid Using:

Many products will bear the word "Patented" or "Exclusive Patented Process". Others will bear the words "Patent Pending". Still other products will say "US PAT.OFF. Number...". This is the only patent information that means anything and even this has little meaning regarding the product effectiveness or whether it is good or bad. One of the oldest jokes amongst chemists is "If you have a unique way to use cow dung in a skin product you could get it patented!", and this is true. Having a patent does not mean your formula is great of better than anyone else's, it merely means you have a formula that is different than anyone else's in varying degrees. Even this can be argued in court if the formula is too close to someone else's and patents are only good for a certain length of time before they have to be re-examined and re-issued.

Some unscrupulous manufacturers have been known to use the word patented or exclusive patented process when in fact they have no patent at all! This is a gamble they hope no one will take the time and trouble to check this out, and many times the gamble pays off. Patent Pending simply means that the manufacturers have *applied* for a patent but does not have it yet. It is not illegal to print this on products, but it is misleading and unethical. And finally, an actual registered patent does not have to even be about the contents. There are also design patents that could be registered for the design of the product packaging! Using the word patent to sell a product is not telling your client anything about it's performance and is in fact a gimmick.

FDA approved!

This statement is the most over used and misunderstood of all gimmicks. How many times has a USA cosmetic company been asked by a European whose eyes are bright with suspicion, "Is your

products FDA approved?" It is not the fault of the Non-American consumer that compels them to ask this question. They have been lead to believe that ALL USA cosmetics have to be FDA approved before selling and that FDA approval means the product is good and really works. This is totally untrue.

The FDA has two *main* categories that they list products under Cosmetic or Drug (medical). To be sure there are a few sub categories that the odd product falls under such as "over the counter medicines" as opposed to Doctor prescribed medicines, aspirin is one of these. But the cosmetic category does not require approval from the FDA as long as all the ingredients in the product are listed in a known reference guide such as MERKS Index or the CTFA reference library as safe for topical use. The FDA is also concerned about claims made on cosmetic products. If a product actually says it changes the structure and nature of the skin, then the FDA will say it is to be medically categorized, thus requires FDA *approval* to be manufactured and sold through the pharmaceutical channels only.

Therefore, cosmetic products do not require FDA approval to sell as long as they are manufactured under FDA safety regulations and do not make big claims. This is why all cosmetic advertisements in the USA use phrases like "Gives the *appearance* of younger skin" or "reveals the younger you" when talking about peeling products. If the claim was "Reverses the aging process" or "Changes the structure of your skin from old to young in six weeks" the manufacturers would be under investigation to prove this. If proven, they would likely be forced to manufacturer as a medical product.

YOUR OWN CLINICAL TRIAL TESTING:

There is one thing you can do as a product distributor that will help give your products real credibility. You can take the time and some expense to conduct your own clinical trials.

Here are two ways:

Clinical Trials: Select 20 clients with similar skin conditions and problems, treat them all with the same protocol for eight weeks keeping detailed records of all applications, products used and results at each treatment. Carefully lit photographs after each treatment, dated on that day, are also necessary. At the end of the session, have the clients write their own observations and experience of the treatment, then sign and date it. Don't forget to get signed permission from the client to use all the data and photographs.

Double Blind Trials: This protocol is performed the same way as the clinical trial with the exception that you would get twenty more clients and perform placebo treatments at the same time. This would mean using all the steps and applications you would use in the clinical trials but in this case you would use some other popular products instead of what you were selling. If group A (clinical group) showed good results and group B (placebo group) did not, by comparison, you would have a good, legitimate double blind testing to refer to in your sales materials. Unfortunately, many manufacturers and distributors do not have the time or money to conduct these types of trials.

Sometimes however, anecdotal luck is with us! Not too long ago a doctor in Finland, Medical Professor Tom Schroder MD, of the Laseri, Helsinki started performing certain topical pre and post laser skin revision treatments based upon theories that he obtained from some of my lectures in that country over the years. He claims that the skin of his patients heals better and grows new healthy cells better after laser than the conventional cortisone cremes and Retin-A normally used for pre and post laser work. He also was convinced that post hyper pigmentation was almost non-existent using the protocol that I suggested. He took these findings to a medical convention and enthusiastically told all the other doctors about what he was doing. They of course said "oh, that's just anecdotal, where are your double blind tests for proof?"

You can imagine my surprise and delight when Dr. Schroder called me and tentatively asked me if he could conduct a double blind test based on my theories and protocol (yeah right, like I was going to say no to a free, long complicated double blind!). The risk I am taking here is that whatever happens over the long test trials he is conducting currently has to be medically published to be taken seriously by the medical field. But it will be published whether the results are great, so-so or bad! I have my fingers, toes and eyes crossed! ■