Pharmaceutical Grade vs. Pharmaceutical Made by Dr. David Seaman

The term *pharmaceutical grade* is commonly used within the nutritional supplement industry to connote purity and quality. It makes us think that pharmaceutical standards have been applied to the nutritional products we buy. In actuality, none of these perceptions properly characterizes the nature of pharmaceutical-grade supplements.

Pharmaceutical-grade refers to the particle size and uniformity of a vitamin, mineral, herb or amino-acid powder. In order to move through encapsulating or tableting machines that are typically designed for drug manufacturing, nutrients need to be "pharmaceutical grade."

Consider as an example that you want to make an oatmeal supplement. It would be impossible for oatmeal flakes to move through a pill-making machine, so they would have to be transformed into a uniform powder that is "pharmaceutical grade." You could do this at home yourself. Take oatmeal flakes and grind them up in a coffee grinder. Now you have oatmeal powder that will flow through a pill-making machine, You now have pharmaceutical-grade oatmeal.

What this means on a practical level is that every supplement you buy is pharmaceutical grade. But don't let this slight-of-hand terminology lead you to believe that there is something special about pharmaceutical-grade supplements based purely on that description.

Pharmaceutical-*Grade* Fish Oil

Using the term *pharmaceutical grade* for fish oils is actually quite erroneous. Before molecular distillation processes were applied to making fish-oil supplements, products were steam distilled. Both molecular and steam distillation removes mercury, dioxins and polychlorinated biphenyls (PCBs), so be wary of those who claim their fish oil is uniquely pure or pharmaceutical because it is has been molecularly distilled.

For the first 20 or more years that fish-oil supplements were available, we most commonly bought steam-distilled products that came in 1,000 mg capsules with 300 mg of omega-3 fatty acids. Molecular distillation allows for omega-3s to be more concentrated, such that now we can get 1,200 mg capsules with 600 mg of omega-3 fatty acids. A prescription version of fish oil called Omacor/Lovaza contains 1,000 mg of oil in the capsule with 840 mg of omega-3 fatty acids.

As described above, omega-3 fatty acids can be concentrated to various degrees. At some point, someone decided to use the term *pharmaceutical grade* to describe the higher-concentrated molecularly distilled fish oil. However, there is no such thing as pharmaceutical-grade fish oil, not even the prescription fish-oil product.

Lack of Regulations

For the vast majority of time that we have purchased nutritional supplements, there were no regulations that required companies to adhere to rigorous manufacturing standards. Supplement manufacturing was kind of like the Wild West, where people took the law into their own hands without receiving substantial punitive measures if they behaved inappropriately.

Several manufacturers realized that regulations were coming to the nutritional-supplement industry because manufacturing issues plague the industry. Many products fail to meet label claims, wrong ingredients are used, microbial contaminants have been identified, and supplements are made in unsanitary environments. To address this problem, the National Products Association (NPA) (**www.naturalproductsassoc.org**) developed a good manufacturing practices (GMP) program for

supplement companies. The purpose was to improve supplement manufacturing standards with an eye to the future, which likely would involve federal regulations.

The GMP program involves an audit. This means that the NPA will inspect a manufacturing facility for proper raw-material handling and subsequent manufacturing processes. The cost is about $3,000 and allows the manufacturer to use the NPA's GMP logo for three years. For such a nominal fee, we might think that most companies would volunteer for an audit to distinguish themselves from other manufacturers. In fact, this is not the case. For most manufacturers, a substantial upgrading of their facility is required in order to successfully pass an audit. These upgrades can cost in excess of $1 million.

A precious few of the companies that provide supplements to the chiropractic profession have an NPA GMP, which means we have no reliable measure of supplement quality and, of course, no company will admit to selling poor-quality supplements. Furthermore, the FDA has recently set guidelines for supplement manufacturing, but it lacks the manpower for substantial oversight.

Pharmaceutical-*Made* Supplements

While several supplement companies have achieved or exceeded the NPA requirements, almost no companies manufacture supplements to pharmaceutical specifications. *Pharmaceutical-made* supplements are very different from the others. If a nutritional supplement is pharmaceutically made, the followings steps are typically involved:

Vitamins, minerals and herbs entering a manufacturing facility are referred to as raw materials. They typically arrive in large garbage-can-size containers. Most are white powders that look the same. However, some vitamins have a color (riboflavin for example) and most herbs are colored as well. Upon receipt of raw materials, they must be cataloged and placed into a quarantine area.

No nutrient can leave the quarantine area for supplement production until it is first identified. In other words, since most nutrients are white powders, each must be identified to make sure that thiamin is actually thiamin, magnesium is actually magnesium, and so on. The laboratory processes for identifying nutrients are published in monographs such as the **United States Pharmacopeia**. For each raw material tested, the process must be documented and cataloged.

Numerous analytical procedures are utilized for identifying raw materials, such as atomic-absorption spectroscopy, fluorescence spectroscopy, fourier transform infrared spectrophotometry, near-infrared capillary spectrophotometry, UV-visible spectrophotometry, capillary electrophoresis, gas chromatography, high-pressure liquid chromatography and inductive coupled plasma mass spectrometry.

Pharmaceutical-made raw materials are also tested for microbial contamination by placing samples into agar plates with growth media for various organisms such as *E. coli* and salmonella. If an herb is placed in an agar plate with growth media, and salmonella grows, this indicates that the raw material is contaminated. If raw materials pass the various laboratory tests, they can be released from quarantine and transferred to a holding area for use in supplement manufacturing.

The most difficult supplement to make is a multivitamin/mineral because so many ingredients are used. A point of interest is that making supplements properly is actually more difficult compared with making medications because nutritional supplements usually contain more ingredients. As mentioned, a multivitamin/mineral is the best example of such manufacturing complexity and difficulty. Additionally, natural ingredients are not always uniform, so standardizing natural materials is a real challenge. Holding natural ingredients to pharmaceutical controls is a constant challenge; color, smell and even potencies have variations.

In the case of a multivitamin/mineral, multiple nutrients are weighed and poured into large blenders, which are commonly the size of an elevator. The blend is then loaded into tableting/encapsulating

machines that are located in environmentally controlled rooms maintained at proper temperature and humidity, and with proper HEPA air filtration.

During the tableting/encapsulating process, supplements are routinely tested to meet standards such as weight, hardness and friability. Finished products are then tested for potency as well as digestibility. Bottles of the finished products are then placed in stability chambers, which function as shelf-life chambers. Tablets are then removed and tested again for potency and contamination. Only after supplements pass through this rigorous process can they be shipped to doctors for dispensing to patients.

Clearly, there is a significant difference between *pharmaceutical-grade* supplements versus *pharmaceutical-made* supplements. If time and location permit, my suggestion is to visit the supplement company you choose to use in your practice (or see if they have a video or other materials that outline their production process in detail from start to finish). This way, you will have a better idea of supplement quality.