Silver facts outshine FDA

Regulators denigrating powerful antimicrobial have no case.

By Scott Tips

Silver has long been known to be a very powerful, broad-spectrum germ fighter that is essentially nontoxic—although we now know it is silver in the ionic form that actually does the work. “Colloidal” silver is an historical way of delivering silver ions to the body. One hundred years ago, it was sold by a major pharmaceutical company, and clinical studies attesting to its efficacy topically and internally were published in prestigious medical journals. However, with the advent of the Food and Drug Administration (FDA) in 1938—and the attendant laws prohibiting disease claims for any product not first so approved by the FDA or grandfathered in—patentable antibiotics soon replaced colloidal silver in the pharmaceutical field. The natural health field never lost sight of silver’s virtues, though, and it has seen growing popularity during the recent few decades.

But now, for some reason, it seems the FDA is trying to rewrite history, and ignore its own literature, in an effort to denigrate colloidal silver—with no data that it can point to in making its case. Some say the reason is very obvious: the threat silver supplements pose to antibiotic profits.

Silver sulfadiazine cream has been used in most burn centers for decades. Catheters and IV needles contain silver to help prevent infection. The faces of stethoscopes are now coated with silver to prevent the transfer of bacteria from one patient to the next. The largest medical products distributor in the United States has been recently touting a new gauze dressing that slowly delivers silver ions in order to fight "drug-resistant” pathogens. Members of the U.S. House of Representatives introduced legislation early this year directing the Secretary of Agriculture to conduct a study of the effectiveness of silver-based biocides as an alternative treatment to preserve wood that people come in contact with in residences and in public places such as restaurants and schools, potentially replacing toxic chromated copper arsenate. The EPA and FDA have recently approved silver ion products for a rapidly growing number of uses, ranging from surface disinfection in medical environments to the inclusion in food handling materials. In all of these cases, the tremendous antimicrobial capabilities and essentially non-toxic nature of silver ions are the prominently emphasized attributes.

During the 1990s, many colloidal silver manufacturers claimed that the grandfather exemption applied to them, since colloidal silver was sold with drug claims prior to 1938. However, in 1999, the FDA issued a Final Rule, finding that no such products met the rigorous grandfathering standards.

The Rule cites numerous reports the FDA has received attesting to the efficacy of various orally ingested silver products, including a very impressive double-blind clinical study showing remarkable efficacy. The Rule states, however, that the studies presented do not meet the statutory bar for drug approval. It repeatedly states they are “not adequate” and “not sufficient” enough to warrant “general recognition” of such silver products as “safe and effective” for “drug” use. Importantly, the Rule does not in any way conclude that the data presented shows such orally ingested silver products are not effective. It says “well-controlled clinical studies… need to be conducted” prior to the allowance of disease claims.

The Rule points out that excessive intake of silver can cause a permanent skin discoloration called “argyria,” and it cites cases of argyria that occurred, almost exclusively, more than fifty years ago—back when FDA-approved silver products contained many thousands of times the silver concentration that modern-day silver supplements do. The Rule does not suggest any restrictions on the sale of such

products other than to say that they may be sold as dietary supplements provided they comply with applicable statutory law and regulations (*e.g.*, the Dietary Supplement Health and Education Act of 1994 - DSHEA).

While there have been a handful of reports of mild cases of argyria in the recent few years (out of perhaps millions of users), argyria is simply not possible when using a silver supplement from a reputable manufacturer according to label directions.

In Food and Water

Silver is naturally occurring in the food and water that we consume, yet you do not see everybody developing argyria. The EPA publishes safety guidelines, based on what is called the Reference Dose (RfD), for what it believes are safe oral intake levels for virtually everything in the environment—including silver. Its safety guidelines for silver pertain explicitly to avoiding argyria, which it states "is a cosmetic effect, with no associated adverse health effects" and "occurs at levels of exposure much lower than those levels associated with other effects of silver." Thus, avoid argyria and silver is harmless.

Reputably made and labeled silver dietary supplements do exist. One such product, which I use myself, is Silver 100 ionic silver complex made by Invision International. If you look at the label for this product, you will see that the label dosing is measured by pounds of body weight, which seems to be the best way to ensure safety and efficiency. Its maximum recommended daily dosage of bio-active ionic silver contains *less silver than may exist in a liter or two of regular drinking water meeting EPA guidelines.*

Some manufacturers inadvertently help the FDA by acting less responsibly. In one instance that I have seen, the manufacturer of a popular 10-ppm colloidal silver product claims that users can consume up to "seven teaspoons" per day and be within the RfD, ignoring the need to first allow for the amount of silver in the food and water intake as is required when referring to the RfD. This could result in consuming *twice* the amount of silver recommended as a daily limit by the EPA's RfD.

Rather than requiring safe dosing levels on labels and in literature, the FDA is instead taking cheap pot-shots at silver.

On December 18, 2002, the FDA issued what it calls the Dietary Supplement Enforcement Report. Putting colloidal silver on a list of "clearly problematic" substances (the report is isolating colloidal silver from all other forms), it states, citing no substantiation at all, nothing more than the following: "These products are promoted as alternatives to antibiotics intended for serious infectious diseases. They also are promoted to protect against anthrax. Colloidal silver is completely ineffective. It is marketed for use by children and can cause severe adverse consequences, including argyria (blue-gray discoloration of the skin caused by the ingestion of silver). This condition is irreversible."

For it to state in this report (it is not law, so read "public relations" or some might even say "propaganda" statement), that colloidal silver is "completely ineffective" while providing zero data to support that contention (let alone exaggerate the safety profile), the FDA seems to forget this is an industry not unknown for its reliance on facts and scientific data and for providing consumers with cutting-edge health products, both of which are apparently an inconvenience to the FDA.

In this regard, I would recommend *www.silverfacts.com* as a more informative source for further information on the legality, safety, and efficacy of ionic-silver and colloidal-silver dietary supplements, including links to the FDA's 1999 Rule on silver, the EPA's safety guidelines on silver, and much more.

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