

# FDA Final Rule On silver and the Silver Lady HORROR Story Brent won't tell you about!

*Source:* <http://sci.tech-archive.net/Archive/sci.med.diseases.lyme/2005-03/0900.html>

---

*a\_weisman\_at\_yahoo.com*

*Date:* 03/25/05

Date: 24 Mar 2005 16:31:41 -0800

Silver:

NOT safe

NOT effective

NOT approved for human use internally

ILLEgal

Don't listen to the LIARS and silver cult profiteers like BRENT THE LIAR!

Don't listen to the silver profiteer cultists!

They LIE

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

[http://www.access.gpo.gov/su\\_d-ocs/aces/aces140.html#fribrowse](http://www.access.gpo.gov/su_d-ocs/aces/aces140.html#fribrowse)

---

SUMMARY: The Food and Drug Administration (FDA) is issuing a-- final rule establishing that all over-the-counter (OTC) drug products c--ontaining

colloidal silver ingredients or silver salts for internal or-- external

use are not generally recognized as safe and effective and a--re misbranded. FDA is issuing this final rule because many OTC --drug products containing colloidal silver ingredients or silver s--alts are being marketed for numerous serious disease conditions and F--DA is not

aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingredients or-- silver salts for these disease conditions.

DATES: This regulation is effective September 16, 1999.

FOR FURTHER INFORMATION CONTACT: Bradford W. Williams, Cente--r for Drug Evaluation and Research (HFD-310), Food and Drug Administrat--ion, 7520

Standish Pl., Rockville, MD 20855, 301-594-0063.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 15, 1996 (61 FR 53685), F--DA published a proposed rule to declare that all OTC drug produ--cts containing colloidal silver ingredients or silver salts are --not generally recognized as safe and effective, and are new drug--s and misbranded within the meaning of section 201(p) of the Feder--al Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). Colloid--al silver

is a suspension of silver particles in a colloidal base. In --recent years, colloidal silver preparations of unknown formulation --have been

appearing in retail outlets. These products are labeled for --numerous disease conditions, many of which are serious diseases. The --dosage form of these colloidal silver products is usually oral, but prod--uct labeling also contains directions for topical and, occasiona--lly, intravenous use.

FDA has not approved a new drug application (NDA) for any co--lloidal silver product. None of the silver salts evaluated as part o--f FDA's

OTC drug review was found to be generally recognized as safe and--effective for its intended use(s). FDA is not aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingre--dients or

silver salts for disease conditions. The agency invited any interested parties to collect and submit any existing data and information that support the safety and effectiveness of colloidal silver ingredients or silver salts for any of the uses not already evaluated under the OTC drug review. Interested persons were invited to submit written comments on the proposed regulation and on the agency's economic impact determination by January 13, 1997.

In response to the proposal, the agency received 251 responses. Copies of these comments are on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Additional information that has come to the agency's attention since publication of the proposal is also on public display in the Dockets Management Branch.

Based on the information set forth in the proposed rule, and after consideration of the information submitted by the public comments (as

summarized as follows), FDA is declaring that all OTC drug products

containing colloidal silver ingredients or silver salts are not generally recognized as safe and effective, and are new drugs and misbranded within the meaning of section 201(p) of the act.

Adequate

safety and effectiveness data have not been provided to establish general recognition of the safety and effectiveness of colloidal silver

or silver salt ingredients for any OTC drug uses. The data submitted

did not include the required absorption, metabolism, tissue distribution, accumulation, excretion, and pharmacodynamics (effect

of

the drug at its action site) of silver in the body, both when taken

internally and applied externally, and of the effect of the particle

size of the silver on these systemic effects.

FDA is amending subpart E of part 310 (21 CFR part 310) to add Sec.

sci.med.diseases.lyme: FDA Final Rule On silver and the Silver Lady HORROR Story Brent won't tell you about!

310.548 for OTC drug products containing colloidal silver  
in--gredients

or silver salts. The agency has expanded proposed Sec. 310.5--48(a)  
to  
include some additional silver ingredients.

...

Silver Lady/colloidal silver/argyria/Rosemary Jacob's story --page  
<http://homepages.together.net/~rjstan/rose1.html>

>>*From Cheryl's Lyme Alt Med Page*

<http://www.aero-vision.com/~ch-eryl/alt.html>:

Colloidal Silver Pros:  
CS PROS

<http://www.wishgranted.com/>

CS Cons:  
Colloidal Silver CONS  
<http://www.quackwatch.com/01QuackeryRelatedTopics/PhonyAds/s-silverad.html>

The Silver Supplement Fraud

Guess who took the colloidal silver (CS)? Rosemary did. That--'s why  
she  
is slate-gray. The condition is called argyria. It is irreve--rsible  
and  
cannot be covered by makeup.

Actually, Rosemary's doctor in New York prescribed CSP for h--er back

in  
the fifties as a treatment for allergies. It was sold as a d--rug  
then.

Today it is sold as a dietary supplement. You can find it in--  
"health  
food" stores and on the Internet. You can even buy the equip--ment to

make your own. It was snake oil when it was given to Rosemar--y. It  
is  
snake oil now.

The only thing Rosemary recommends CSP for is a gray skin dy--e. She  
knows that it is safe, effective, and permanent when used fo--r that  
purpose. She also knows that being a gray person in a black --and  
white

world can have a serious negative impact on your social and  
--economic  
life.

Promoters claim that CSP prevents and cures 650 diseases inc--luding  
Aids and cancer. They say that people with even a trace of s--ilver  
in  
their bodies don't get sick!

Both Rosemary and the FDA have asked them for their proof. A--ll they

get are quotes from old quacks who manufactured the stuff at-- the  
turn

of the century, misquotes from reputable authors and wonderf--ul  
anecdotes. "I've taken it everyday for four years and feel g--reat,"  
the  
saleslady says.

The only problem Rosemary has with the anecdotes is that the--y are  
selectively chosen to sell CSP. The promoters refuse to incl--ude her

negative anecdotes or those of all the other argyric people  
--recorded

in the medical literature. Rosemary had breast cancer at the-- age of

42. The silver in her body made her face so gray that the nu--rses in

pre--op thought that she was in cardiac arrest! The promoters-- won't  
tell you this though.

The FDA has told the promoters that if they want to continue-- making

medical claims for CSP they will have to first have it appro--ved as  
a

drug. Of course, that doesn't stop them from selling the stu--ff as a

"dietary supplement." It just prevents them from legally wri--ting  
their

claims on the label or putting them in their ads.

And, oh yes, if you do decide to use CSP, have the product a--nalysed

by

an independent lab. According to the dietary supplement indu--stry  
itself, a lot of the stuff tested that is labelled colloidal-- silver

really isn't. You see "dietary supplements," thanks to inten--se  
industry lobbying are unregulated by any government agency. --So very

often what is on the label isn't in the bottle. In fact, wha--t is in

the bottle may even be something more toxic than CSP. Buyer --beware!

P.S. Rosemary will gladly provide you with documentation and references. Just ask!

Here's Rosemary's story in her words...

<http://homepages.together.net/~rjstan/rose2.html>

Rosemary's Story

ROSEMARY JACOBS

Background

For forty years I tried to blend into the crowd, but when I discovered that the quacks were back, I knew that I couldn't-- do that anymore. I had to stand up and shout, "Look at me! I'm gray.--" I had

to warn the public. A local newspaper broke my story with the headline, "The silver woman from Long Island. The face that no one for--gets."

I wasn't always gray. I was born white in Brooklyn, New York--, in 1942.

When I was eleven years old, my mother mentioned to an MD ---- an eye, ear, nose and throat specialist on Long Island -- that I alw--ays had a

cold. He told her that it had to be allergies and prescribed-- nose drops that contained silver with instructions to take them "intermittently as needed."

Rosemary, Mom, the family dog

Diagnosis

Right after starting high school at the age of 14, my friend--s and I

volunteered to work in the local hospital as "candy strippers--." The hospital was run by a Catholic order of nursing sisters who --required that all new volunteers attend a class at their convent once-- a week

on Saturday mornings. The nun who gave the course was also a nu--rse and

a

pharmacist. One morning when I walked in she was very startl--ed by my

appearance.

"Why are you that color?" she asked. What color? No one had --noticed

that my color was weird until then. She repeated, "Why are y--ou that

color? Ask the doctor." Suddenly everyone noticed. I was  
sla--te--gray.

We had a family friend, a general practitioner, who made an  
appointment for me to see a dermatologist. Meanwhile, Saturd--ay  
rolled

around again and I went back to class. This time Sister gree--ted me  
with, "You're taking nose drops, aren't you?" I told her I w--as.  
"Stop," she said. "They have silver in them. That's why you'--re  
gray."

She had seen another nursing sister at the hospital with the-- same  
skin  
discoloration which was also caused by nose drops, probably --from  
the  
same doctor who was on their staff. The dermatologist took o--ne look

at  
me and diagnosed argyria – a permanent, irreversible skin  
discoloration caused by the ingestion of silver.

A biopsy confirmed the diagnosis showing all the little spec--ks of  
silver in my skin. Unfortunately, that is the only informati--on that

I

have ever been able to get about the drug that disfigured me--. No  
one  
ever sued doctors back then.

When as a young adult I had difficulty getting jobs because-- people  
didn't like my appearance, the lawyers I consulted told me t--hat New

York is one of the few states with a statute of limitations --on  
malpractice suits. I never really wanted to sue the doctor. --He was  
a  
good person who made a tragic mistake. He read the ads from --drug  
companies instead of the medical literature. (1)(2)(3)

Old Garbage

All kinds of silver medicinals, as well as many other dubiou--s and  
noxious drugs, were used by desperate physicians before the --advent  
of

antibiotics. Any student of history can tell you how ineffective they

were.

Colloidal silver (CSP) is not a new alternative remedy. It is an old,

discarded traditional one that homeopaths and other people calling themselves "alternative health-care practitioners" have pulled out of

the garbage pail of useless and dangerous drugs and therapies, things

mainstream medicine threw away decades ago.

In 1935 Gaul & Staud wrote about colloidal silver in The Journal of

the American Medical Association (JAMA), "The alarming increase of argyrosis leaves little doubt as to our purpose in this report.

There

has been an accumulation of indubitable clinical evidence which makes

it imperative to present before those who prescribe, dispense or use

these drugs the danger entailed therein...The obvious responsibility

for this injudicious medication rests with the circularized advertisements by the various manufacturers to the physician;" (4)

In 1940 Bryant added, "Conscientious observers in the field of otolaryngology can no longer doubt the occurrence of generalized argyria caused by intranasal silver medications," and "A persistent

indifferent attitude to this on the part of otolaryngologist might be

condoned if it were possible through the use of such medication to achieve beneficial results for the patient which could not be achieved

otherwise, but quite the contrary is the case."

He goes on to state that these silver preparations should be supplanted by a weak ephedrine or neosynephrin in an isotonic solution. (5) He continues, "The use of silver-containing nasal medication over even a few weeks is dangerous and accomplishes nothing

that cannot be accomplished safely and more efficiently by other

means." (6)

#### The New Old Miracle

In 1995 I discovered that CSP, one of the drugs that causes --argyria, was again being aggressively promoted. It was being sold ove--r the Internet where you could buy equipment to make your own, in --"health

food stores" and by MLMs (multilevel marketers). Promoters w--ere claiming that silver is an "essential mineral" and that even-- a trace amount in the body prevents serious illness. They also claim--ed that

it was a pre-1938 OTC (over--the--counter drug) that cures 650 sp--ecific conditions and diseases such as cancer, AIDS, acne, and lupu--s. They

passed off their promotional material on the Internet and in-- books and magazines as if it were the gospel truth.

I thought the promoters were ignorant people who had made a --terrible mistake, but when I contacted several of them and discovered-- that they were not interested in hearing my story, they would not chan--ge their ads and they refused to include my negative anecdotes along --with their positive ones, I knew that they weren't ignorant.

They were quacks who were deliberately lying to sell their p--roduct.

The response I got from the owner of a store that sells the --stuff was

pretty typical. I told him that my skin is gray from the ing--estion of

silver adding that silver in my body has never benefited me.-- I had breast cancer at the age of 42. In the year that I was born,-- 1942, a

Dr. Levine wrote an article in the New England Journal of Me--dicine stating that all doctors had seen cases of argyria, but it w--as rarely

reported in the medical literature. (7) In searching that li--terature

for thirty years I have never found any evidence that silver-- in a person's body benefits anyone other than the quack who sold --it.

If, in fact, it did do all the wonderful things that the pro--moters claim, Queen Victoria and the Rockefellers would still be al--ive and

they would be gray like me.

I gave the merchant a fist full of medical literature to sub--stantiate

my claims and asked for proof that the product he sold with --the colloidal silver label on it was in fact safe and effective --for something, anything. I wanted to know how he knew that it ac--tually did

all the great things claimed and how he knew that it wouldn'--t cause

argyria. He said he'd have to contact his supplier and get b--ack to me.

The "Evidence"

When he phoned and said that he had the material I had reque--sted, he

added that he didn't think it would interest me.

How wrong he was.

He wasn't there when I went to pick it up. His wife, visibly uncomfortable with me in the store, seemed to be hoping that-- I'd glance at the "evidence" and leave. Instead, I asked if I co--uld take

it next door to copy. Reluctantly, she agreed.

What a gold mine that turned out to be. The same names, Dr. --Henry Crookes, Sir Malcolm Morris, A. Legge Roe, and R.J. Hartman ---- to name

a few -- kept popping up in all the promotional material. Wh--ile most

promoters pretended that these people were contemporary rese--archers,

some of the material that the store owner gave me contained --citations

with dates. These "authors" were ancient.

Old Quacks

I went to the nearest medical history library and pulled the citations. Henry Crookes was a pioneer CSP manufacturer in E--ngland at

the turn of the century. (8) He sold many different alleged --colloidal

preparations under the Collosol trade name. (9) Collosol Arg--entum was

the brand name of his colloidal silver. (10) Malcolm Morris --was rumored to be on his board of directors. (11)

In 1919 JAMA's Council on Pharmacy and Chemistry ruled that --Collosol Argentum, along with several other of the Crookes' Laborator--y products, were "inadmissible to New and Nonofficial Remedies--," stating that "In the few cases in which the therapeutic claims for t--hese preparations were examined, the claims were found to be so i--mprobable

or exaggerated as to have necessitated the rejection of thes--e products." (12)

Further down in the same article referring to Collosol Hydra--rgyrum and Collosol Ferrum they said that, "If either of these preparat--ions were

injected intravenously as directed, death might result, maki--ng the physician morally if not legally liable." (13)

A. Legge Roe did write about the great success he had treati--ng gonorrhoeal opthamalia with collosol argentum. He also state--d, "It is

the most useful preparation that has been placed in our hand--s since the introduction of cocaine." (14)

In 1939 Hartman, a chemist not a medical doctor, included a --chapter on colloids in medicine in his chemistry book. On p.536 he said-- that CSP

is safe enough to be put into the eyes and nose. He also sta--ted on the same page that, "Intramuscular injections of colloidally sus--pended lead are of value in arresting certain cancerous growths." (--15) His

source for all the material on colloids in medicine was Croo--kes Laboratories.

I felt as if I were doing quack genealogy. A quack quoting a-- quack quoting a quack.

#### Misquoted Reputable Authors

Another article about silver that colloidal silver promoters-- often referred to was one by Jim Powell which appeared in the March 1978 edition of the now defunct popular magazine Science Digest. --They always referred to it as "Our Mightiest Germ Fighter."

When I tracked down the magazine, I discovered that the article didn't mention colloidal silver and that the full title was, "Perhaps it soon will be recognized as OUR MIGHTIEST GERM FIGHTER."

Why do you think promoters never mention the first half of the title?

Could it be because they know that the promise never materialized and

they don't want readers to find out?

Another reference constantly appearing in the quack promotional material is the book ARGYRIA, (16) which truly is the definitive work

on the subject. It was written in 1939 by Hill and Pillsbury--. Promoters say that it states that "properly prepared colloidal silver" never caused argyria and that 95 percent of the cases resulted from silver nitrate.

What the book really says, and I'm probably one of the few people on earth who has a copy, is that in a study of 214 cases for which data was available, "silver nitrate is the responsible compound in over half the cases. Again it must be pointed out that the number of cases

due to other compounds may be no real indication of their relative capacity for the production of argyria, but rather an evidence of their popularity as a medicinal agent." (17)

Regarding CSP, "It is impossible to make a definitive statement concerning the amount of a colloidal silver compound which may be instilled into a body cavity without the possibility of argyria." (18)

The authors called for further studies and warning labels on all silver medicinals. (19) They also pointed out that it had never been

determined whether or not individual susceptibilities exist.-- Are some

people more likely to develop argyria than others? (20) We s--till don't know.

Hill & Pillsbury added, "there is no evidence indicating tha--t the giving of extremely small amounts of silver over a prolonged-- period

in any way lessens the danger of argyria from any given amount --of silver

compound." (21)

In 1975 Goodman & Gilman stated that, "There is no acceptabl--e evidence that the routine use of silver solutions for the prophylaxis-- of colds

or other respiratory tract infections is at all efficacious,-- and cases of argyria have resulted from this practice. Fortunately, th--e colloidal silver preparations are now in a deserved oblivion--." (22)

There is no animal model for argyria. (23) It can take decad--es to develop. (24) There have been reported cases in which it did-- not appear until several years after the drug was discontinued. --(25)

Silver workers have developed argyria, presumably from inhal--ing silver dust. (26) One person's skin discoloration was caused by the electrolytic action between a gold and a silver filing. Sali--va caused

the silver to go into solution. (27)

1990s Snake Oil

Contrary to promoters' claims, we still ingest silver in our-- diets.

(28) Some drinking water contains silver. At what concentrat--ion of silver does drinking water turn into CSP? I've never been ab--le to get

a salesperson to tell me this. Hopefully all they are really-- selling is very expensive, distilled water, but no one knows for sur--e since

CSP is now sold as a "dietary supplement." As such it is unr--egulated

by any government agency. Only the manufacturer knows what's-- in the  
bottle.

On p. 26 of the April 1997 issue of Vegetarian Times, a maga--zine  
that

promotes supplements, it states that the National Nutritiona--l Foods

Association (NNFA), a trade group in Newport Beach, CA, says-- that  
"some metal colloid products have been found to be high in t--oxic  
metals such as aluminum. Others have no detectable levels of-- the  
desirable metal listed on the label." NNFA advises consumers-- taking

colloidal silver to have it analyzed by an independent labor--atory.

A doctor told me that he had a bottle of CSP prepared by a  
p--harmacist

analyzed and discovered that it was just very expensive tap --water.

I

find it very interesting that probably thousands of people a--re all  
reporting similar wonderful health and medical benefits from--  
products

that only have one thing in common, the labels all say "coll--oidal  
silver."

I believe this is ample proof that individuals and doctors a--re not  
capable of determining whether or not a drug is safe and eff--ective.

Scientific investigations start with anecdotal evidence, but-- they  
don't end there.

Index

<http://homepages.together.net/~rjstan/rose3.html>

Silver Fraud

<http://homepages.together.net/~rjstan/rose1.html>

My Story

<http://homepages.together.net/~rjstan/rose2.html>

FAQs

<http://homepages.together.net/~rjstan/rose6.html>

Links

<http://homepages.together.net/~rjstan/rose10.html>

E-mail

mailto:rjs...@together.net

=====  
Colloidal Silver: Risk without Benefit

<http://www.quackwatch.org/01QuackeryRelatedTopics/PhonyAds/s-ilverad.html>

Colloidal Silver:  
Risk Without Benefit

Stephen Barrett, M.D.

Colloidal silver is a suspension of submicroscopic metallic silver particles in a colloidal base. Long-term use of silver preparations

can lead to argyria, a condition in which silver salts deposit in the

skin, eyes, and internal organs, and the skin turns ashen-gray.

Many

cases of argyria occurred during the pre-antibiotic era when silver

was a common ingredient in nosedrops. When the cause became apparent,

doctors stopped recommending their use, and reputable manufacturers

stopped producing them. The official drug guidebooks (United States

Pharmacopeia and National Formulary) have not listed colloidal silver

products since 1975.

Dubious Ads In recent years, silver-containing products have been marketed with unsubstantiated claims that they are effective against

AIDS, cancer, infectious diseases, parasites, chronic fatigue, acne,

warts, hemorrhoids, enlarged prostate, and many other diseases and conditions. Some marketers claim that colloidal silver is effective

against hundreds of diseases.

During 1997 and 1998, Changes International, a Florida-based multilevel company, stated:

Our colloidal silver contains 99.99% pure silver particles suspended indefinitely in demineralized water that kills bacteria and viruses.

It can be applied topically and/or absorbed into the bloodstream sublingually (under the tongue), thereby avoiding the negative effects of traditional antibiotics that kill good bacteria in the lower digestive tract.

An all natural antibiotic alternative in the purest form available.

The presence of colloidal silver near a virus, fungi, bacterium or any other single celled pathogen disables its oxygen-metabolism enzyme, its chemical lung, so to say. The pathogens suffocates and dies, and is cleared out of the body by the immune, lymphatic and elimination systems.

Unlike pharmaceutical antibiotics which destroy beneficial enzymes, colloidal silver leaves these beneficial enzymes intact. Thus colloidal silver is absolutely safe for humans, reptiles, plants and all multi-celled living matter.

It is impossible for single-celled germs to mutate into silver-resistant forms, as happens with conventional antibiotics. Also, colloidal silver cannot interact or interfere with other medicines being taken. Colloidal silver is truly a safe, natural remedy for many of mankind's ills. Colloidal silver can be taken indefinitely because the body does not develop a tolerance to it [1]

Seasilver International,  
<http://www.seasilver.com/>

a California-based multilevel company, claims that Americans are suffering from "silver deficiency." Although silver is not an essential nutrient, product information posted on the company's Web site states:

The depletion of minerals in our soil has left us deficient of silver, one of our most essential trace minerals, causing a drastic increase in immune system disorders in our society in the last decade. Research has taught us that all disease is allowed to manifest itself because of a weakened immune system. In over 20 years of worldwide research on Colloidal Silver, numerous interviews with government agencies, health care practitioners and their patients, no other nutrient, herb or drug (prescription or over-the-counter) is as safe and effective against

all known forms of unfriendly virus, bacteria, and fungus.  
Additionally, while it is generally known that most antibiotics  
kill  
only perhaps 6 or 7 different disease organisms, reports have shown

that Colloidal Silver has been used successfully in the treatment  
of  
over 650 diseases! Furthermore, strains of disease organisms fail  
to  
develop in the presence of Colloidal Silver. Colloidal Silver's  
greatest attribute is its unique ability to function as a superior  
second immune system in the body! [2]

The ad below is from the July 1996 issue of Alternative Medicine  
Digest.

[ad won't copy and paste go to site if you want to view it]

#### Critical Studies and Case Reports

In 1995, an herbal distributor named Leslie Taylor tested nine  
commonly marketed colloidal silver products available at  
health-food  
stores and concluded:

Two of the products were contaminated with microorganisms.

The amount of silver suspended in solution varied from product to  
product and would gradually decrease over time.

Only five products actually showed antibacterial activity in a  
laboratory test. To perform the test, she prepared a culture plate  
with Staphylococcus aureus bacteria, which can cause infections in  
humans. She then placed a drop from each product on the plate and  
used  
disks of two common antibiotics as controls. After eight hours of  
incubation, she found that bacterial growth had been inhibited  
around

the antibiotics and four of the products.

Of course, the fact that a product inhibits bacteria in a  
laboratory  
culture doesn't mean it is effective (or safe) in the human body.  
In  
fact, products that kill bacteria in the laboratory would be more  
likely to cause argyria because they contain more silver ions that  
are  
free to deposit in the user's skin.

FDA laboratory studies have found that the amount of silver in some

product samples has varied from 15.2% to 124% of the amount --listed on

the product labels. The amount of silver required to produce-- argyria is unknown. However, the FDA has concluded that the risk of --using silver products exceeds any unsubstantiated benefit [3]. So --far, nine

cases of argyria related to silver products have been report--ed: A 56--year--old man who had sold and used colloidal silver for-- three years, developed blue/gray discoloration of his fingernails accompanied by a very high blood level of silver [4].

A married couple who had three years of daily consumption of-- a drink prepared by administering an electrolytic charge to a bowl o--f water

that contained a silver bar [5]. Another couple had been taking a silver--containing "dietary supplement" prescribed by a naturopath [5].

A mentally ill man who had been drinking silver--containing h--erbal tea

for about 10 months [5].

Stan Jones, Montana's Libertarian Party candidate for the U.S. Senate, who reportedly started taking colloidal silver-- in 1999

for fear that Y2K disruptions might lead to a shortage of an-tibiotics. He made his own concoction by electrically two silver wires --in a glass of water [6].

Two men, ages 63 and 76, developed argyria after a year of p--roduct use inspired by Internet claims [7]. Enforcement Actions

Between October 1993 and September 1994, the FDA issued warn--ing letters to five colloidal silver marketers::

Higher Education Library Publications (H.E.L.P.), of Springf--ield, Utah, was ordered to stop claiming that its colloidal silver-- product was effective as a natural antibiotic and might be effective-- against cancer, genito--urinary diseases, tuberculosis, and AIDS. Nutrition, Inc., of Arvada, Colorado, was ordered to stop st--ating or

implying that its Silvicidal, when administered orally or intravenously, was nontoxic, FDA-approved, and was a broad-spectrum

antibiotic that killed bacteria and all virus and fungal infections.

In addition, it was falsely claimed to be effective against a long list of specific diseases.

Reseau International of Cincinnati, Ohio was ordered to stop claiming

that its colloidal silver product was a "natural antibiotic and anti-inflammatory immune system stimulant" and that it was effective against cancer, staph, strep, influenza, general body infections, inflammation, impaired immune system, fungus toxicity, tonsillitis,

Meniere's symptoms, whooping cough, shingles, syphilis, cholera, and malaria. The labeling also stated that colloidal silver could cause

major growth stimulation of human tissues and can regenerate

Silverado Inc., of Bountiful, Utah, was warned to stop making false

claims that its colloidal silver product was effective as an antibiotic, anti-inflammatory, anti-viral, and anti-fungal agent and

that it could stimulate the immune system.

Unic, of Carmichael, California, was ordered to stop claiming that its

colloidal silver product was effective against many diseases and could

heal burn-damaged tissue without scarring.

In October 1996, the FDA proposed to ban the use of colloidal silver

or silver salts in over-the-counter products [8]. A Final Rule banning

such use was issued on August 17, 1999 and became effective September

16th. The rule applies to any nonprescription colloidal silver or silver salt product claimed to be effective in preventing or treating

any disease [9]. Silver products can still be sold as "dietary supplements" provided that no health claims are made for them.

During

2000, the FDA issued warnings to more than 20 companies  
<http://www.fda.gov/cder/warn/c-yber/cyber2000.htm>  
whose Web sites were making illegal therapeutic claims for  
colloidal  
silver products.

In 2000, the Federal Court of Australia banned Vital Earth Company  
Pty  
Limited and its director Darryl John Jones from falsely  
representing  
that the colloidal silver produced by their "Vital Silver 3000  
Zapper," "Vital Silver 2000 Automatic" and "Vital Silver 2000":

Can kill all disease-causing bacteria, fungi and virus within six  
minutes of contact  
Has no harmful side effects; that colloidal silver could be used as

an  
antibiotic for all the acquired diseases of active AIDS

Is effective with more than 650 different pathogenic bacteria and  
virus types  
Has been used successfully against diseases including AIDS,  
cholera,  
diabetes, leprosy, leukemia, lupus, skin cancer, syphilis and  
whooping  
cough.

The company was also ordered to pay AUS\$9000 in costs and to  
provide  
refunds [10].

In 2001, the FTC obtained consent agreements with two companies:

Robert C. Spencer and Lisa M. Spencer, doing business as Aaron  
Company  
(Palm Bay, Florida). Colloidal silver has been medically proven to  
kill over 650 disease-causing organisms in the body and is  
effective  
in curing diseases ranging from cancer and multiple sclerosis to  
HIV/AIDS [11].

ForMor, Inc., doing business as ForMor International, and its  
president, Stan Gross (Birmingham, Alabama) agreed not to make  
unsubstantiated claims that colloidal silver is effective in  
treating

over 650 infectious diseases, has no adverse side effects, and is  
effective against arthritis, blood poisoning, cancer, cholera,  
diphtheria, diabetes, dysentery, gonorrhea, herpes, influenza,  
leprosy, lupus, malaria, meningitis, rheumatism, shingles, staph  
infections, strep infections, syphilis, tuberculosis, whooping

cough,

and yeast infections [11].

In 2002, the FTC obtained a consent agreement with Kris Pletschke, doing business as Raw Health, <http://www.rawhealth.net/> agreed to stop making unsubstantiated claims that its colloidal silver product could

treat or cure 650 different diseases; eliminate all pathogens in the human body in six minutes or less; and is medically proven to kill every destructive bacterial, viral, and fungal organism in the body, including anthrax, Ebola, Hanta, and flesh-eating bacteria [12].

In 2002, the Australian Therapeutic Goods Administration amended its rules so that water-treatment products containing substances like colloidal silver for which therapeutic claims are made must meet the requirements of medicines included in the Australian Register of Therapeutic Goods. This means that such products can no longer be legally marketed without proof that they are safe and effective for

their intended purpose. The amendment was based on conclusions that:

There is little evidence to support therapeutic claims made for colloidal silver products;

The risk to consumers of silver toxicity outweighs the value of trying an unsubstantiated treatment, and bacterial resistance to silver can occur

Efforts should be made to curb the illegal availability of colloidal silver products, which is a significant public health issue [13].

## References

1. Product brochure. Changes International, 1997. Downloaded in 1998.

Seasilver International Product Information

<http://web.archive.org/web/199-81207065006/seasilver.com/productinfo.htm>

, accessed October 12, 1998.

2. Fung MC, Bowen DL. Silver products for medical indications: risk-benefit assessment

<http://www.ncbi.nlm.nih.gov/en-trez/query.fcgi?cmd=Retrieve&d-b=PubMed&...>

Journal of Toxicology and Clinical Toxicology 34:119–26, 19--96.

4. Gulbranson SH and others. Argyria following the use of dietary supplements containing colloidal silver protein.

<http://www.ncbi.nlm.nih.gov/en-trez/query.fcgi?cmd=Retrieve&d-b=PubMed&...>

Cutis 66:373–374, 2000.

5. Hori K and others. Believe it or not — Silver still poisons!  
Veterinary and Human Toxicology 44(5):291–292, 2002.

6. Blue Is the color of my candidate's skin.

[http://www.foxnews.com/printer-friendly\\_story/0%2C3566%2C646-92%2C00.html](http://www.foxnews.com/printer-friendly_story/0%2C3566%2C646-92%2C00.html)

Associated Press, Oct 2, 2002

7. Cohen LE and others. Effects of Internet quackery: Argyria in the silver state. Federal Practitioner 21(4):9–17, 2004.

8. Federal Register

[http://www.access.gpo.gov/su\\_d-ocs/aces/aaces002.html](http://www.access.gpo.gov/su_d-ocs/aces/aaces002.html)

61:53685–53688, 1996. (To access this document, search the 1--996 volume for "colloidal silver.")

9. FDA. Final rule: Over-the-counter drug products containing colloidal silver ingredients or silver salts.

<http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdo-cID=06028...>

Federal Register 64:44653–44658, 1999. Download PDF version

<http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdo-cID=06028...>

10. Refunds for buyers of alternative therapy devices.

<http://www.accc.gov.au/media/m-r2000/mr-87-00.htm>

News release, Australian Competition and Consumer Commission., May 5, 20

11. "Operation Cure.All" wages new battle in ongoing war against Internet health fraud

<http://www.ftc.gov/opa/2001/06-/cureall.htm>

12. . FTC news release, June 14, 2001.

FTC announces first two enforcement actions against purveyors of bioterrorism defense products.

<http://www.ftc.gov/opa/2002/02-/vitalraw.htm>

FTC news release, Feb 27, 2002.

13. Regulation of colloidal silver and related products.

<http://www.tga.health.gov.au/d-ocs/html/csilver.htm>

Therapeutic Goods Administration Web site, Aug 19, 2003.

For Further Information

Rosemary Jacobs

<http://homepages.together.net/~rjstan/>

, an argyria victim, has made a detailed study of the colloidal silver

marketplace and is willing to answer questions.

mailto:rjs...@together.net

This article was revised on May 5, 2004.

---

Between October 1993 and September 1994, the FDA issued warning letters to five colloidal silver marketers::

\* Higher Education Library Publications (H.E.L.P.), of S-pringfield, Utah, was ordered to stop claiming that its colloidal silver product was effective as a natural antibiotic and might be effective against cancer, -genito-urinary diseases, tuberculosis, and AIDS.

\* Nutrition, Inc., of Arvada, Colorado, was ordered to stop stating or implying that its Silvicidal, when administered orally or in-travenously, was nontoxic, FDA-approved, and was a broad-spectrum antibiotic --that killed bacteria and all virus and fungal infections. In addition, i--t was falsely

claimed to be effective against a long list of specific dise--ases.

\* Reseau International of Cincinnati, Ohio was ordered to stop claiming

that its colloidal silver product was a "natural antibiotic --and anti-inflammatory immune system stimulant" and that it was e--ffective

against

cancer, staph, strep, influenza, general body infections, in-flammation,

impaired immune system, fungus toxicity, tonsillitis, Menier--e's symptoms,

whooping cough, shingles, syphilis, cholera, and malaria. Th--e labeling also

stated that colloidal silver could cause major growth stimu--ation of

human

tissues and can regenerate

\* Silverado Inc., of Bountiful, Utah, was warned to stop making false

claims that its colloidal silver product was effective as an antibiotic, anti-inflammatory, anti-viral, and anti-fungal agent and that it could stimulate the immune system.

\* Unic, of Carmichael, California, was ordered to stop claiming that its colloidal silver product was effective against many diseases and could heal burn-damaged tissue without scarring.

In October 1996, the FDA proposed to ban the use of colloidal silver or silver salts in over-the-counter products [7]. A Final Rule banning such use was issued on August 17, 1999 and became effective September 16th. The rule applies to any nonprescription colloidal silver or silver salt product claimed to be effective in preventing or treating any disease [8]. Silver products can still be sold as "dietary supplements" provided that no health claims are

made for them. During 2000, the FDA issued warnings to more than 20 companies whose Web sites were making illegal therapeutic claims for colloidal silver products.

In 2000, the Federal Court of Australia banned Vital Earth Company Pty Limited and its director Darryl John Jones from falsely representing that the colloidal silver produced by their "Vital Silver 3000 Zapper," "Vital Silver 2000 Automatic" and "Vital Silver 2000":

\* Can kill all disease-causing bacteria, fungi and virus within six minutes of contact

\* Has no harmful side effects; that colloidal silver could be used as an antibiotic for all the acquired diseases of active AIDS

- \* Is effective with more than 650 different pathogenic b-act-eria and virus types

- \* Has been used successfully against diseases including -AID-S, cholera, diabetes, leprosy, leukemia, lupus, skin cancer, syphilis an--d whooping cough.

The company was also ordered to pay AUS\$9000 in costs and to-- provide refunds [9].

In 2001, the FTC obtained consent agreements with two compan--ies:

- \* Robert C. Spencer and Lisa M. Spencer, doing business -as -Aaron Company (Palm Bay, Florida). Colloidal silver has been medically pro--ven to kill over 650 disease--causing organisms in the body and is effective i--n curing diseases ranging from cancer and multiple sclerosis to HIV/AIDS [10].

- \* ForMor, Inc., doing business as ForMor International, -and- its president, Stan Gross (Birmingham, Alabama) agreed not to make unsubsta--ntiated

claims that colloidal silver is effective in treating over 650 infectiou--s diseases, has no adverse side effects, and is effective against arthritis, bl--ood poisoning, cancer, cholera, diphtheria, diabetes, dysentery, gonorrhea,-- herpes, influenza, leprosy, lupus, malaria, meningitis, rheumatism, shingles, s--taph infections, strep infections, syphilis, tuberculosis, whooping cough, an--d yeast infections [10].

In 2002, the FTC obtained a consent agreement with Kris Plet--schke, doing business as Raw Health, agreed to stop making unsubstantiate--d claims that its colloidal silver product could treat or cure 650 different d--iseases; eliminate all pathogens in the human body in six minutes or less; and --is

medically proven  
to kill every destructive bacterial, viral, and fungal organ--ism in  
the body,  
including anthrax, Ebola, Hanta, and flesh--eating bacteria [--12].

In 2002, the Australian Therapeutic Goods Administration ame--nded  
its  
rules so  
that water--treatment products containing substances like col--loidal  
silver for  
which therapeutic claims are made must meet the requirements-- of  
medicines  
included in the Australian Register of Therapeutic Goods. Th--is  
means  
that such  
products can no longer be legally marketed without proof tha--t they  
are safe and  
effective for their intended purpose. The amendment was base--d on  
conclusions  
that:

- \* There is little evidence to support therapeutic claims- ma-de for  
colloidal  
silver products;
- \* The risk to consumers of silver toxicity outweighs the- va-lue of  
trying an  
unsubstantiated treatment, and bacterial resistance to silve--r can  
occur
- \* Efforts should be made to curb the illegal availabilit-y o-f  
colloidal  
silver products, which is a significant public health issue --[11] .