

**Presented to Members of The House International  
Relations Committee Subcommittee on Africa, Global  
Human Rights, and International Operations**

**Written Testimony**

**of**

**William D. Moeller**

**President, American Biotech Laboratories  
80 West Canyon Crest Road  
Alpine, Utah 84004**

**April 26, 2005**

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## **INTRODUCTION**

Good Morning. I am William D. Moeller, Chairman and President of American Biotech Laboratories of Alpine, Utah ("ABL"), a company which produces engineered, metallic silver, nano-sized particles in water-based products. Our engineered silver particles have performed far beyond anyone's expectations as anti-microbial agents, against a staggering variety of microbes such as malaria, flesh-eating bacteria (MRSA – Methicillin Resistant Staphylococcus aureus) and E.coli.

Whether used on surfaces as disinfectants or if taken internally as supplements, all of our ABL products are non-toxic and have no known adverse human side effects. Our products have surprised many experts in the medical and science worlds because of their ability to combat bacteria, yeast, and viruses. ABL products have been proven to destroy anthrax spores and bubonic plague bacteria on surfaces, to eliminate the malaria parasite in humans and a host of other beneficial results.

We have developed five products to date as well as several other new products currently in our product development pipeline. We manufacture all of our products in the United States. One product ASAP-AGX-32 (a water solution containing 32 ppm of our engineered silver nano-particles) has already been approved by the EPA as a surface disinfectant for hard, non-porous surfaces in commercial, residential, industrial, hospital and medical environments. Another product called Silgel is a non-toxic moisturizing gel, which utilizes our ASAP-AGX-32 as a raw material supply of silver particles. It is currently undergoing the final steps for FDA approval for the treatment of lacerations, first and second degree burns, abrasions, surgical wounds, skin ulcers etc. Several other new ABL products will soon warrant the filing of new FDA and/or USDA applications.

## **BACKGROUND**

All my life I have been involved with the mining and processing of silver in Utah. I am Chairman of the Board of Clifton Mining, a Utah mining company holding several million ounces of silver reserves. My family and I are large stockholders in Clifton Mining. I have spent most of my life in Utah where my wife Jeneane and I raised our seven children together.

In the late 1990s, the price of silver reached a point where its mining and production costs were above its selling price. At that time, we needed to find an alternative use for silver that at least paid for removing the silver from the rock ore. We decided to devote some the resources of Clifton mining to try to create a new water-based product containing silver. Since ancient times it has been known that silver inherently possesses desirable antimicrobial and immune boosting properties. We planned to be the first to maximize those desirable effects of silver. We did our homework and found a plethora of colloidal silver products and devices littering the marketplace, most of which did not seem very sophisticated to us. Our analyses of various colloidal silver products (mainly dietary supplements) led us to the conclusion that these manufacturers lacked stature in the marketplace and the products produced were, at best, anecdotally effective.

In 1998 we created ABL with the idea of manufacturing high quality, standardized colloidal silver products. I talked all five of my sons into joining ABL in what we thought might be a nice family business. We worked hard inventing new methods to purify and standardize our silver products and, frankly, got a little lucky along the way because we ended up inventing and manufacturing something else all altogether.

Our initial discoveries are the subject of two issued US Patents: 6,214,299, which issued on April 10, 2001 and related US Patent 6,743,348, which issued on June 1, 2004 (See *Appendix I*). Additional discoveries are contained in several other pending patent applications, most of which are not yet in the public domain.

Although ABL's initial products were referred to as "colloidal silver," we now know that our engineered particles are quite different. When most people use the phrase "colloidal silver," they mean ionic silver, silver salts or silver nitrate in a gelatin matrix. ABL's liquid products do not contain ionic silver, silver salts or silver nitrates. Rather, they contain engineered nano-sized particles of metallic silver dispersed in a matrix of pure water. Although these products are primarily water (99.999%)

because the actual silver concentration is so low. Their unique potency has been demonstrated by numerous laboratory (in vitro) and human (in vivo) tests carried out by ABL, at ABL's request, and in some of the most interesting cases, without ABL's involvement or even contemporaneous knowledge.

ABL's first three products that we manufactured were dietary supplements. These products have actual silver concentrations of 10 parts per million ("ppm"), 14 ppm and 22 ppm and are sold through a number of different outlets. For example, ASAP 10 (the 10 ppm product) is being sold through General Nutrition Center stores throughout the country under the name *Silver Biotics*. This 10 ppm of silver particles in purified water is colorless, tasteless, odorless and is non-toxic. Based on our knowledge of the engineering of the metallic silver particles, we estimate the actual shelf life of our products to be in excess of 10 years.

As demand for our products grew, we began distributing ASAP 10 worldwide. In short order, many different positive antidotal stories began to pour in from around the world. The interest in our product grows and certain private investors joined our core "family and friends" group. One user's experience led to an important event that would forever open our eyes to the power of our 10 ppm ASAP non-toxic liquid.

In 2001, twelve bottles of our 10 ppm ASAP product fell into the hands of a medical Doctor in Rwanda, Dr. Ewabuhihl Ezechias. One day I received a frantic telephone call from Dr. Ezechias' office that was in Rwanda caring for a group of very young children who were in the last stages of malaria about to die. Dr. Ezechias was looking for instructions on how to administer our ASAP 10 product to these desperately ill children. I suggested to the Doctor that he measure out a teaspoon or two to each of the children, two or three times a day and that he repeat the process until the children hopefully showed some improvement. He responded abruptly that there was no time for measuring anything – the situation was far too grave for "such niceties." All of these children had temperatures around 105 degrees, had not improved with conventional treatments and were all about to die. He asked me if he could simply put the water into their bottles. Knowing of its totally non-toxic properties and sensing his desperation, I assured him that it would not hurt the children.

Days later, Dr. Ezechias contacted and told me that he had put the ASAP 10 ppm water directly into the drinking water bottles of 11 of these children. All 11 of the young children who received the ASAP 10 ppm got better. A week later, the 11 left his clinic alive and healthy. Sadly, there were other children

who did not receive the ASAP treatment. Those children died in spite of receiving all the conventional treatments which Dr. Ezechias provided them. This affected me deeply and I realized that our ASAP 10 ppm had potent, positive effects on malaria patients. Besides the phone calls, we also received an indirect written communication from Rwanda which is included in *Appendix 2*.

Word spread quickly and soon scientists and medical doctors from around the world began to hear stories about ABL's silver products. One doctor from Mumbai, India, Dr. Dilip Mehta of Viridis BioPharma decided to check out the many stories. Without our knowledge, he began to test our products in a variety of different ways against several different micro-organisms. Dr. Mehta scientifically tested and compared our products with other silver-based products from around the world. Dr. Mehta concluded that no other product in the world had the biological efficacy of our non-toxic ASAP 10 ppm product. Traveling half-way around the world from India to Utah, Dr. Mehta unexpectedly showed up at our Alpine facility to begin a trusted and fruitful association advancing our knowledge and product base.

We also have met many important scientists along our journey, including Professor Rustum Roy who concurrently holds appointments with Pennsylvania State University, Arizona State University, and the University of Arizona. Professor Roy is a world leading materials scientist (please refer to [www.rustumroy.com](http://www.rustumroy.com)) whose initial interest was in determining and characterizing the physical properties of our water products. Because he was interested in water and its relationship to general health, Professor Roy wanted to correlate physical properties of ABL's water-based silver products with their superior biological performance. He found that our ASAP 10 and ASAP-AGX-32 water-based products are physically quite different in a number of inherent, measurable, physical properties from colloidal silver products. Professor Roy has now generated much data showing that our products are unique. Professor Roy has presented this data at several scientific conferences. Please see Professor Roy's letter in *Appendix 3*.

Professor Roy, in turn, introduced us to General Resonance, a cutting-edge science and technology company located in Maryland, whose work and expertise Professor Roy had scrutinized and tested at the Materials Research Laboratory at Penn State. ABL and General Resonance recognized their potential synergy and have formed a joint venture. The combination of General Resonance's fundamental understandings and its patented sciences and technologies with ABL's existing products and technologies promises to generate a long-lasting pipeline of new, more potent products with a

broad use spectrum (or even targeted specifically to particular diseases). Other joint ventures are likely. Clearly there has been much interest generated in ABL's new non-toxic products.

## **THE TECHNOLOGY**

ABL manufactures its water-based products by controlling and delivering a few thousand Volts AC through highly purified silver electrodes in contact with the surface of high purity water. The silver in the electrodes is slowly dispersed into the water as metallic silver nano-sized particles. These engineered silver particles currently vary in size between about 10-50 nanometers in diameter, depending on the particular manufacturing conditions. Concentrations as low as 1-2 ppm have been shown to have efficacy against certain bacteria and viruses, however, the products being sold right now typically range in concentration of from 10 ppm – 32 ppm (i.e. ASAP 10 and AGX 32, both of which are greater than 99.999% pure water). These concentrations have been shown to kill or de-activate bacteria and viruses in a few minutes. *Appendix 4* shows in brief summary form certain in vitro results and data which demonstrate the broad spectrum efficacy of ABL silver-water solutions against a variety of microbes (and related human diseases).

The data in *Appendix 4* (along with other data not presented today) suggest that small amounts of selectively engineered silver particles can have dramatic anti-bacterial, anti-fungal, and anti-viral effects. Surface disinfectants (e.g., bleach) and most pharmaceutical products against these agents of disease function by various chemical reactions and are consumed and used up in the process. These agents that are consumed in this way must be replenished to remain effective. Our silver particles function differently and it is clear from ongoing research that our engineered silver particles are not consumed in chemical reactions the way other anti-microbial agents are. Rather, it appears that the silver particles function as catalysts, which promote certain lethal reactions in only unfriendly microbes (i.e., the destruction of bacteria, fungi and viruses). This is the same way platinum particles in an automobile's catalytic converter function. They promote lethal reactions in pollutants without being consumed in the process. We believe that this understanding is very important and partly explains the lack of any known negative biological side effects from the ABL products. If engineered properly, very small amounts of catalytic silver apparently can go a very long way.

## **MALARIA STUDIES**

After ABL learned how the lives of the 11 young children in Rwanda were saved (discussed above) ABL initiated contact with four different hospitals/clinics in Ghana. We shipped to these different medical facilities about 1000 of our 8 ounce bottles of ASAP 10. Obtaining good follow-up clinical data turned out to be quite difficult because once the patients felt better; they simply did not come back for further treatment and follow-up. For example, *Appendix 5* contains representative data from the Justub Clinic, run by Dr. Agnes Abraham, who reported after her first trials, that typically their patients return to the clinic only if they are still ill, which was not the case with their patients treated with the ASAP 10.

Another preliminary trial occurred at the Air Force Hospital in Ghana where the Medical Officer in Charge was Dr. Evelyn Kwabiah. The five patients treated by Dr. Kwabiah all had positive outcomes (see *Appendix 6*). Dr. Kwabiah reported that patients with malaria who had received the ASAP 10: recovered faster than those receiving conventional treatments; recovered where conventional treatments had failed; or, that the ASAP 10 functioned as a prophylactic preventing the recurrence of malaria.

Ultimately, the success of ABL's ASAP 10 ppm against malaria gained such widespread acceptance in Ghana that the Food and Drugs Board of the Republic of Ghana issued a Certificate of Registration of a Drug for ABL's product (see *Appendix 7*).

Although we were receiving better clinical reporting, and Ghana had issued a Certificate of Registration, we still were not satisfied that the previous trials met the level of standardization we wanted to achieve. To obtain better data concerning ASAP 10's effectiveness against malaria, ABL (in cooperation with competent university medical professionals) designed a new protocol (see *Appendix 8*). The new protocol required that all Malaria patients be monitored for 15 days and were encouraged to return for follow-up testing and assessment with financial incentives (patients were paid a few dollars a day to come back and be monitored and tested). *Appendix 8* contains the study protocol, results, and one representative patient's chart. (An Executive Summary of these more reliably executed Malaria Studies in Ghana, supported by ABL, is shown in *Appendix 9*).

Study #3 listed in *Appendix 9* was the most reliable of the studies and used the protocol described in *Appendix 8*. The data showed that out of the 41 Malaria patients (ages 1-90 years) involved in the studies and receiving ASAP 10, all 41 people survived and there were no treatment failures. All



participating patients were deemed to have achieved full recovery in an average of 4.5 to 6.5 days, with recovery time differences probably being due in part to differences in total dosages. Clearly the data suggest that ABL's ASAP 10 ppm product, when administered in 2-3 teaspoon quantities 2-3 times per day (i.e., one ounce per day) reverses malaria and saves lives. The cost of this regimen in total is a few dollars and appears to be highly effective.

No undesirable or drug-like side effects were reported by any of the patients in any of these more rigorous studies. We believe that this was because the ASAP 10 ppm is primarily water with very small amounts of catalyst-like metallic silver particles therein,. This result is also quite different from all other known malaria treatments, which often involve quite uncomfortable side effects.

ABL has continued its efforts to determine the effectiveness of its ASAP 10 ppm product as an effective treatment against malaria. To that end, ABL sought the input of various malaria experts including that of Dr. Awa Marie Coll-Seck, Executive Secretary of the *Roll Back Malaria Partnership* hosted by the World Health Organization. Dr. Coll-Seck provided her comments which were instrumental in creating a proposed 660 patient study; initially to be performed in Senegal. This Protocol was just completed earlier this month, but has not yet been initiated. ABL hopes to be able to accomplish this or a similar study in the near future so that we can begin to have a larger impact on malaria worldwide.

## **TUBERCULOSIS**

Preliminary data generated by two independent laboratories suggest an efficacy of ASAP 10 ppm and ASAP-AGX-32 against tuberculosis. But, because this data is new and not yet reviewed, we are reluctant to share any of the data at this time. However, we are encouraged by what we have seen.

## **OTHER PRODUCTS OF INTEREST**

### **1. Surface Disinfectant.**

ABL received EPA approval for ASAP-AGX-32 in 2003 (see *Appendix 10*). ABL also received a contract (Contract No. V797P-5762X) with the VA Hospitals, to use this product as a surface



disinfectant. *Appendix 11* shows data recently generated by an independent laboratory comparing AGX-32 to eight leading disinfectants for use against Methicillin resistant Staphylococcus aureus (MRSA). The data is reported two different ways: (1). “% Effectiveness,” which compares how effective the leading disinfectant is compared to AGX-32 (e.g., “Phenol” is 40% as effective as AGX-32); and (2) “Coefficient,” which shows the reverse or how much better AGX-32 is relative to the leading disinfectant (e.g., AGX-32 is 2.5 times more effective than Phenol). These data are very significant because AGX-32 is a non-toxic product, unlike most disinfectants, and yet functions as well or better than the other disinfectants. It can be used around hospitalized patients without any ill effects. Moreover, because the silver functions akin to a catalyst, it is not consumed in a chemical process and will continue to disinfect a surface until removed (e.g., by soap and water) from the surface on which it was applied.

## **2. Wound Care and Burn Care.**

ABL has a 510(k) application pending with the FDA (see *Appendix 12*) for AGX SILGEL, a moisturizing gel containing ABL engineered silver particles. ABL expects the final animal study required for this FDA approval for wound care to be finished in June 2005. We anticipate that approval will be obtained for use of the SILGEL silver-gel product on: lacerations, abrasions, skin tears, leg and other surface ulcers, surgical wounds, first and second degree burns etc. The base material for manufacturing this product is ASAP-AGX-32 (a non-toxic precursor). This AGX SILGEL product is a broad spectrum, anti-microbial. SILGEL is not cytotoxic in studies performed to date (e.g., the gel has been proven to be non-toxic in the oral route, by mouse model studies up to 5000mg/kg of body weight). ABL’s silver-gel provides moisture for wound healing and burn treatment, has no color or smell, requires no refrigeration and remains stable from 17-113 degrees Fahrenheit. In FDA approval comparison studies, AGX SILGEL was found to be over 10 times more effective in killing MRSA compared to a leading FDA approved silver-based product (at a challenge of about 10,000,000 bacteria/ml), even though the leading and approved product contains more than 300 times as much silver than AGX SILGEL.<sup>1</sup>

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<sup>1</sup> This product has not been offered for sale due to the pending FDA Application.

Dr. John A. Shaw, a practicing oncologist in Arizona, has recently been using AGX Silgel on an experimental basis to treat radiation burns from radiation therapy used for treating breast cancer. His reviewed work has been conducted at hospitals in Arizona. His initial findings are that the AGX Silgel promotes healing more effectively than other commercially available products. A letter from Dr. Shaw is included in *Appendix 13*.

### **GOVERNMENT ACTIVITIES OF INTEREST**

ABL has initiated a number of recent US Government contacts, which have resulted in the testing of ASAP-AGX-32 and AGX Silgel products (or at least the desire to test). Many of these contacts have generated desirable data showing the efficacy of ABL's products for different uses. We have not offered these products for sale to the government yet.

Letters of support for ABL from Senator Orrin Hatch and Lt. General Paul K Carlton, Jr., addressed to The Honorable Tom Ridge, can be found in *Appendix 14*.

### **CONCLUDING STATEMENT**

ABL has invented and patented a process and a product that should have wide applicability to a variety of bacterial, fungal and viral species. The production process is robust and can be quickly scaled-up to meet virtually any production demands. The ASAP 10 ppm product, in quantities of about 1 ounce per day, seems to eliminate the symptoms of malaria in human patients in about 4-6 days. Thus, one 8 ounce bottle of ABL's ASAP 10 ppm has been more than enough to eliminate the symptoms of malaria in each of the patients involved in the African studies. ABL is ready to make this product (or the process) available on a world-wide basis. We hope that the Committee will be sufficiently impressed to help us to help others.

# **APPENDIX 1**

# **APPENDIX 2**

**My dear Mr. Colby,**

**As usual you never cease to amaze me. When you were last here you helped us get started on a hospital and cleaning up our water problems.**

**The bottles of the ASAP liquid did what you said it would do. We administered it by putting it in baby bottles and allowing the child to drink as much as he/she wanted. The results were not instantaneous as you thought but it did stop the malaria.**

**I am sure you will find in your testing how much dosage is needed. We feel here in Rwanda you again have put us first. After reviewing your testing we will order from your Gryphon Group enough to eliminate this disease and hold in reserve enough for any recurrence.**

**You hinted at other uses. We will talk of these on your next visit.**

**Sincerely your friend,**



**Ezechias M.N.**

# **APPENDIX 3**



**Rustum Roy**

**The Pennsylvania State University  
102 Materials Research Laboratory  
University Park, PA 16802**

**Telephone: (814) 865-3421  
Fax: (814) 863-7040, -7039  
Cell phone: (814) 883-9024  
E-mail: [rroy@psu.edu](mailto:rroy@psu.edu)  
<http://www.mrl.psu.edu>**

*Evan Pugh Professor of the Solid State Emeritus • Professor of Geochemistry, Emeritus • Professor of Science, Technology and Society, Emeritus  
Visiting Professor of Medicine, University of Arizona • Distinguished Professor of Materials, Arizona State University*

April 22, 2005

To Whom It May Concern,

During the last several months, the individuals and Institutions listed below have joined together to create a world class virtual laboratory utilizing the widest range of experimental tools for determining the structure and properties, including health effects, of water as a major health vector. In that context we have been introduced to several engineered metallic silver nano-particle products manufactured by American Biotech Laboratories (ABL).

Detailed state of the art materials characterization including Scanning and Transmission Electron Microscopy (TEM), Raman Spectroscopy and Infrared Spectroscopy, viscosity, surface tension and acoustic attenuation, etc., have been conducted in our various laboratory facilities. The uniquely successful health effects that have appeared in various in vitro and in vivo trials (both internal and external) in the ABL products, have been correlated to the unique Raman and TEM signatures of the engineered silver nano-particle products made by ABL. It is evident to us that the current ABL products (as well as the now predictable improvement products) offer a major opportunity, to be studied further in great detail as the prototype of such products, so that the U.S., and the world, may all benefit from this knowledge.

We are impressed with ABL's products and are interested in utilizing our combined national leadership skills in the areas of materials analysis, chemistry and alternative medical therapies, to collaborate with ABL (and their joint venture partner, General Resonance) to further understand and develop new and improved nano-products based on nearly pure water.

Yours very sincerely,

and Prof. Iris Bell, Director of Res. PIM, Univ. of Arizona  
and Prof. S. Dey, Dept. of Materials, Arizona State Univ.

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# **APPENDIX 4**

<u>Disease</u>	<u>Pathogen</u>	<u>Effective Concentration</u>
Boils	<i>Staphylococcus aureus</i>	Killed @ 5 ppm
Osteomyelitis	<i>Staphylococcus aureus</i>	Killed @ 5 ppm
Bacillary Dysentery	<i>Shigella boydii</i>	Killed @ 2.5 ppm
Burn Infections	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Dental Plaque	<i>Streptococcus mutans</i>	Killed @ 5 ppm
Diarrhea (Bloody)	<i>Shigella boydii</i>	Killed @ 2.5 ppm
Diarrhea	<i>Escherichia coli</i>	Killed @ 2.5 ppm
Ear Infection	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Ear Infection	<i>Streptococcus pneumoniae</i>	Killed @ 2.5 ppm
Enteric Fever	<i>Salmonella typhimurium</i>	Killed @ 2.5 ppm
Epiglottitis (In children)	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Eye Infections	<i>Staphylococcus aureus</i>	Killed @ 5 ppm
Corneal Ulcers-Keratitis	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Food Poisoning	<i>Salmonella arizonae</i>	Killed @ 5 ppm
Food Poisoning	<i>Salmonella typhimurium</i>	Killed @ 2.5 ppm
Food Poisoning	<i>Escherichia coli</i>	Killed @ 2.5 ppm
Endocarditis	<i>Streptococcus faecalis</i>	Killed @ 2.5 ppm
Endocarditis	<i>Streptococcus gordonii</i>	Killed @ 5 ppm
Meningitis	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Meningitis	<i>Enterobacter aerogenes</i>	Killed @ 2.5 ppm
Meningitis	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Meningitis	<i>Streptococcus pneumoniae</i>	Killed @ 2.5 ppm
Meningitis	<i>Klebsiella pneumoniae</i>	Killed @ 2.5 ppm
Nosocomial Infections	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Nosocomial Infections	<i>Streptococcus pyogenes</i>	Killed @ 1.25 ppm
Nosocomial Infections (From hospitals)		
Pneumonia	<i>Staphylococcus aureus</i>	Killed @ 5 ppm
Pneumonia	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Pneumonia	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Pneumonia	<i>Streptococcus pneumoniae</i>	Killed @ 2.5 ppm
Respiratory Tract Infections	<i>Streptococcus pyogenes</i>	Killed @ 1.25 ppm
Respiratory Tract Infections	<i>E. coli</i>	Killed @ 2.5 ppm
Respiratory Tract Infections	<i>Klebsiella pneumoniae</i>	Killed @ 2.5 ppm
Scarlet Fever	<i>Streptococcus pyogenes</i>	Killed @ 1.25 ppm
Septicemia	<i>Enterobacter aeropyogenes</i>	Killed @ 2.5 ppm
Sinus Infections	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Sinusitis	<i>Streptococcus pneumoniae</i>	Killed @ 2.5 ppm
Impetigo	<i>Staphylococcus aureus</i>	Killed @ 1.25 ppm
Skin Infections	<i>Staphylococcus aureus</i>	Killed @ 5 ppm
Skin Infections	<i>Streptococcus pyogenes</i>	Killed @ 1.25 ppm
Strep Throat	<i>Streptococcus pyogenes</i>	Killed @ 1.25 ppm
Suppurative Arthritis	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Throat Infections	<i>Haemophilus influenzae</i>	Killed @ 1.25 ppm
Tooth Decay	<i>Streptococcus mutans</i>	Killed @ 5 ppm
Urethritis (Men)	<i>Trichomonas vaginalis</i>	Killed @ 10 ppm
Urinary Tract Infections	<i>E. coli</i>	Killed @ 2.5 ppm
Urinary Tract Infections	<i>Klebsiella pneumoniae</i>	Killed @ 2.5 ppm
Urinary Tract Infections	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Urinary Tract Infections	<i>Streptococcus faecalis</i>	Killed @ 2.5 ppm
Urinary Tract Infections	<i>Enterobacter aeropyogenes</i>	Killed @ 2.5 ppm
Vaginitis (Women)	<i>Trichomonas vaginalis</i>	Killed @ 10 ppm
Wound Infections	<i>Escherichia coli</i>	Killed @ 2.5 ppm
Wound Infections	<i>Enterobacter aeropyogenes</i>	Killed @ 2.5 ppm
Wound Infections	<i>Klebsiella pneumoniae</i>	Killed @ 2.5 ppm
Wound Infections	<i>Pseudomonas aeruginosa</i>	Killed @ 5 ppm
Wound Infections	<i>Streptococcus faecalis</i>	Killed @ 2.5 ppm
Yeast Infections	<i>Candida albicans</i>	Killed @ 10 ppm

# **APPENDIX 5**

CLINIC/HOSPITAL: Jastub Clinic  
MEDICAL OFFICER IN CHARGE: Dr. Agnes Abraham

ADDRESS: Box 99, Kasoa

SIDE 1

STUDY RESULT OF EFFICACY OF AMERICAN BIOTECH LABS ASAP SOLUTION AGAINST  
MALARIA

PATIENT NAME & ID	AGE	DATE ASAP ADMINSTD DAY/MO/YR	DOS	Before ASAP Administered		Subsequent test after ASAP administration		TOTAL MLs FOR EFFTV CURE	TOTAL MLs FOR EFFTV CURE	GENERAL OBSERVATION AND REMARKS
				Date	Result	Date	Result			
Ralph Dixon 01118	1	17/06/03	5ml tds	17/6/03	BF++, + Fungal inf. + Bronchial Pneumonia			5ml tds	7days	Patient didn't report back
Yaw Ekwan	5	10/6/03	5ml bd	10/6/03	BF+, after Chloroquin + Fungal	17/7/03	Mps Neg. Fungal Healed	5ml tds	2 weeks	Was treated for 2 weeks due to fungal infection
Kwame Andoh Q322	70	17/6/03	5ml tds	17/6/03	Mps + & Lobar Pneumonia			10ml tds	10days	Patient didn't report back for test. Pt. Was detained for 2days

# STUDY RESULT OF EFFICACY OF AMERICAN BIOTECH LABS ASAP SOLUTION AGAINST MALARIA

PATIENT NAME & ID	AGE	DATE ASAP ADMINSTD DAY/MO/YR	DOS	Before ASAP Administered		Subsequent test after ASAP administration		TOTAL Mls FOR EFFTV CURE	TOTAL Mls FOR EFFTV CURE	GENERAL OBSERVATION AND REMARKS
				Date	Result	Date	Result			
Kwame Baah Baidoo	90	19/6/03	10mlb d	19/6/03	BF ++ & Fungal inf.			10mlbd	7days	Patient didn't report back
Kofi Mensah Q341	25	19/6/03	10mlb d	Bf ++ ESR 40ml				10mlbd	10days	Suspected Tuberculosis patient didn't report back
Priscilla Amoah Q347	21	19/6/03	10ml	Bf ++ HB 7.5gm/d c				10mlbd	7days	Patient didn't report back
Karnell Harmon	22	19/6/03	10mlb d	17/6/03	BF +, + Giardia Lambria in stool	28/6/03	No Mps No Giardia	10mlbd	1week	Conditions improved. Giardia Lambria - Neg
Terrance Blay	12	19/6/03	5ml tds	19/6/03	BF ++			5ml tds	5days	Patient didn't report back Had URTI and Helminthiasis too

# **APPENDIX 6**

STUDY RESULT OF EFFICACY OF AMERICAN BIOTECH LABS ASAP SOLUTION AGAINST  
 MALARIA

PATIENT'S NAME	AGE	DATE ASAP ADMINSTD DAY/MO/YR	DOS	Before asap Administered		Subsequent test after Asap administration			TOTAL Mls F/ CURE	TOTAL Mls F/ CURE	GENERAL OBSERVATION AND REMARKS
				Date	Result	Date	Result	Date			
Mis Joyce	28	15th Nov 2002	1 tsp 3x x3 Days	15/11/ 02	BF ++	19/11/ 02	No mps	21/11/ 03	No mps	45ml	4days  Symptoms of general malaria subsided practically after first 2 doses
Mr Nketiah	42	2nd Dec 2002	1 tsp 3x x 3days	2/ 12/02	BF +	5/12/0 2	No mps			45ml	3-4 days  Had milder symptom, recovery earlier than other cases
Cpl Ak	32	12th sept 2003	1 tsp 3x x 3days	11/ 09 03	BF +++	15/09 /03	No mps			45ml	3days  Pt had 2 courses and malarials (chloroquine - Artesunate but still had +++ after ASAP mps was Nil



**STUDY RESULT OF EFFICACY OF AMERICAN BIOTECH LABS ASAP SOLUTION AGAINST  
MALARIA**

PATIENT'S NAME	AGE	DATE ASAP ADMINSTD DAY/MO/YR	DOS	Before asap Administerd				Subsequent test after Asap administration				TOTAL MIs F/ CURE	TOTAL MIs F/ CURE	GENERAL OBSERVATION AND REMARKS
				Date	Result	Date	Result	Date	Result	Date	Result			
Capt Kwabiah	36	Since 2002 till date	1 tsp per week											Used to have recurrent malaria, Takes weekly prophylactic dose of 1 tablespoon. Presently hardly falls ill with malaria
Sandra Otuo (SCD)	5	weekly dose Dec 2002	weekly dose of 5ml											Occurrence of crises often induced by malaria subsided almost 90%

# **APPENDIX 7**

# FOOD AND DRUGS BOARD

Republic Of Ghana



Certificate No: HONA0001

## Certificate of Registration of a Drug

Food and Drugs Law 1992 ( PNDCL 305B ) SEC. 18

*This is to certify that*

ASAP (SILVER) SOLUTION CLASS: HOMOEOPATHIC  
is registered for use in Ghana and is subject to the provisions of the Food and Drugs  
Law, 1992 ( PNDCL 305 B ) and the Food and Drugs  
( Amendment ) Act, 1996 ( Act 523 )

Active ingredients ( s ) / Strength ..... PURIFIED SILVER ..... 10ppm/5ml.....

Applicant : AMERICAN BIOTECH LABS., ALPINE UTAH, USA.....

Manufacturer : AMERICAN BIOTECH LABS., ALPINE UTAH, USA.....

Local Agent : FAECON LTD., TAKORADI.....

Registration No. : HP01-0002 ..... Date of Registration : JULY 2001.....

The validity of this certificate shall continue until JULY 2004 unless  
otherwise suspended, revoked or varied as to the period of its validity.

Dated this 19TH day of SEPTEMBER 2002

  
G H A N A  
Chief Executive

Food and Drugs Board

# **APPENDIX 8**

**PROTOCOL FOR TESTING ASAP SOLUTION (10ppm) IN THE  
TREATMENT OF MALARIA**

**American Biotech Labs, Alpine, Utah  
Manufacturers of American Silver's Anti-Bacterial  
Product (ASAP)**

The purpose of this protocol is to devise a procedure whereby the ASAP Silver Solution produced by American Technology Laboratories can be tested for its' curative properties in treating patients who have contracted a Malaria infection with any of the four (4) Plasmodium species. An overview of the protocol is as follows:

The testing shall be carried out in medical clinics or hospitals which are equipped with or have access to laboratory facilities for the specified test and by medical Doctors who are familiar with the disease and its health ramifications. There will be a total of 16 patients examined per doctor, and the patients will be required to take the silver product twice a day for five days, as well as have their blood drawn one day before the trial begins, and then every day until the blood test shows that the parasite has been eliminated for at least two days. The patients will only be paid if they adhere completely to the schedule for taking the silver and for obtaining the daily blood tests; if they conscientiously follow the requirements for the protocol, the patients who volunteer will be compensated at a negotiated daily rate for each day in the period on total compliance with the protocol specified for the complete test. ie, they take the silver each of the five days as instructed, and that they come in each day as required to have their blood tested for the presence of the malarial parasite. Details of Protocol:

Number of patients to be tested per physician: 16; 8 males and 8 females

Total number of days for the trial: 15

Dose of ASAP Silver Solution (10 ppm) to be given for treatment of patients: A total daily dose of one ounce of ASAP Silver Solution (10 ppm) divided into two equal doses, one-half ounce (3 tsp) taken in the morning and one-half ounce (3 tsp) taken in the evening. The patients will be treated with the ASAP Silver Solution for the first five (5) days of the total 15 day trial, or if the parasite is not completely gone by day five, silver treatment will continue until the parasite is gone, on until day 15, which ever occurs first.

In the event of a patient whose parasites are gone by day two or three, the silver will be continued until day five, and a note made in the records as when the parasite was completely gone.

In the event of a patient who is still harboring parasite after having taken the silver for 15 days, the trial will be terminated as usual, and this patient recorded as a failure to cure in the records.

For the patient who is cured in less than five days, the date of complete parasite disappearance is recorded, the patient continues to receive silver until day five, and continue in the trial to day 15.

**Blood tests:**

Blood tests to be used: The presence (or absence) of parasites in the patients blood will be determined by either the Acridine Orange stain test, or the Giemsa stain test, on thin or thick blood smears from each of the patients. The patients blood will be tested on day zero (0) to ascertain that they do, in fact, have an active case of malaria. If the blood test confirms an active case of malaria, then that patient will be screened for acceptance into the trial. Screening will include recording of vital data such as name, age, patient reported onset of disease, informing the patient of what will be required of them during the trial, what they will be paid for full compliance, and the fact that failure of compliance will result in being dropped from the trial with no remuneration. For patient that agree to joining the trial, they will be given a written set of instructions telling them how to take the silver product each day, where to go each day for their blood tests, and emphasizing the necessity of complete adherence to the protocol of the trial in order to be paid for any of the days. Include in these written instructions what they will be paid if they successfully do everything required of them in the trial.

Remuneration of physicians: Each physician will be paid a total of \$1000.00 (dollars).

When all appropriately kept and signed records have been received by American Biotechnology Labs representatives in Ghana.

The attached form has been proposed for the recording of the test results over the fifteen continuous day's period specified for the test. Observations made in cases of other multiple infections in the course of the treatment of the patient infected with malaria, may be recorded at the back of the form provided. Elaborations or clarifications on the malaria treatment results may also be recorded at the back of the report form.

CLINICAL TEST RESULTS OF THE TREATMENT OF MALARIAL WITH ASAP SOLUTION (10PPM)  
A PRODUCT OF AMERICAN BIOTECH LABS, ALPINE UTAH

CLINIC/HOSPITAL: JUSTAS CLINIC MATERNITY ADDRESS: P.O. BOX 99, KATHA GATHAN

MEDICAL OFFICER IN CHARGE: DR. (MRS) AGNES ABRAHAM CONTACT PHONE: 0244806923

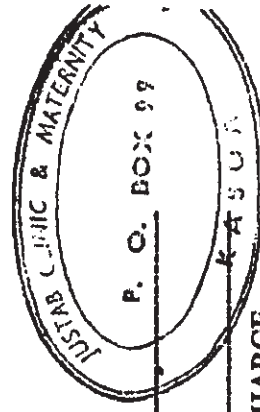
NAME OF PATIENT: MAWUPEMOR MENSAT AGE: 16 YRS GENDERS: MALE

CONFIRMATION DATE OF MALARIA INFECTION: 2/8/04 LEVEL OF INFECTIONS: (++) M.P.S

Test Day	Date Asap Administered	Daily Dosage	Clinical Test Results for Malaria Parasites	Observation and Remarks
1	4/8/04	15ml bd	(++)	Chills, fever, headache
2	5/8/04	15ml bd	(+)	Improving.
3	6/8/04	15ml bd	No mps	Feels well
5	7/8/04	15ml bd	No mps	Well
6	9/8/04	15ml bd	No mps	Well.
7	10/8/04	15ml bd	No mps	Well



Test Day	Date Asap Administered	Daily Dosage	Clinical Test Results for Malaria Parasites	
8	11/8/04	Stopped	No mps	Very well
9	12/8/04	✓	No mps	Very well
10	13/8/04	✓	No mps	Very well
11	14/8/04	✓	No mps	Very well
12	16/8/04	✓	No mps	Very well
13	17/8/04	✓	No mps	Very well
14	18/8/04	✓	No mps	Very well
15	19/8/04	✓	No mps	Very well
	20/8/04	✓	No mps	Very well



SIGN: Magel

DATE: 20/8/04

MEDICAL OFFICER INCHARGE

Dr. Agnes Honohan

NB: Please use the back of the form for further clarification or elaboration for other observations made in the course of the Malaria treatment.

# **APPENDIX 9**

# American Biotech Labs

## Malaria Studies Executive Summary

(This data is intended for government and military use only.)

### Introduction

Three human studies on Malaria have now been completed using American Biotech Labs ASAP Solution. The three studies summarized herein, took place in four hospitals in Ghana, West Africa. The first two tests were completed as part of larger more general studies, that were designed to test the product on a variety of human diseases, and to establish effective dosages. Only the work on Malaria is summarized herein. The third study was completed under strict protocols, and was completed with the direct intent to study the effectivity of a specific dose of the ASAP Solution product on human cases of Malaria. The third study was completed with all patients receiving the exact same dosage of the product, under the same time-frames and with their blood checked daily for the existence and levels of the Malaria parasite. American Biotech Labs has three more protocol controlled, human Malaria studies currently underway in two different countries of Africa. The three additional studies are expected to be completed within the next 60 days.

### Study # 1

- \* Number of participants in the study: (11).
- \* Age range of study patients youngest/oldest: (8/75 years).
- \* Sex of participants male/female: NA.
- \* Average dosage of ASAP Solution given daily: 10 ml (two teaspoons) three times daily.
- \* Average number of days until improvement was noted by the doctors: (2.4 days).
- \* Average number of days of product usage to achieve full recovery as deemed by the doctors:(5.0 days).
- \* Shortest recovery time reported for full recovery: (3 days).
- \* Longest recovery time reported for full recovery: (7 days).
- \* Number of patients whose blood was checked (post treatment) for the existence of the Malaria plasmodium: none.
- \* Number of treatment failures that occurred in the study: (0) There were no treatment failures!

### Study # 2

- \* Number of participants in the study: (16).
- \* Age range of study patients youngest/oldest: (1/90 years).
- \* Sex of participants male/female: NA.
- \* Average dosage of ASAP Solution given daily: 5ml (one teaspoon) three times daily.
- \* Average number of days of product usage to achieve full recovery as deemed by the doctors:

(6.33 days).

- \* Shortest recovery time reported for full recovery: (3 days).
- \* Longest recovery time reported for full recovery: (10 days).
- \* Number of patients whose blood was checked (post treatment) for the existence of the Malaria plasmodium: (7 patients).
- \* Number of checked patients whose blood tested negative for the Malaria plasmodium: all seven patients that were checked were found to be completely negative for the plasmodium.
- \* Number of treatment failures that occurred in the study: (0) there were no treatment failures!


### **Study # 3**

- \* Number of participants in the study: (16).
- \* Age range of study patients youngest/oldest: (2/61 years).
- \* Sex of participants male/female: (8/8)
- \* Dosage of ASAP Solution given daily: 15ml. (Three teaspoons) given twice daily.
- \* Average number of days until no MPS were found in the blood (tested daily): (3.43 days)
- \* Average number of days of product usage to achieve full recovery as deemed by the doctors: (4.31 days)
- \* Shortest recovery time reported for full recovery: (2 days).
- \* Longest recovery time reported for full recovery: (8 days).
- \* Number of patients whose blood was checked (post treatment) for the existence of the Malaria plasmodium: all patients were checked daily for 14 days.
- \* Number of checked patients whose blood tested negative for the Malaria plasmodium: all patients tested negative for the plasmodium within 6 days.
- \* Number of treatment failures that occurred in the study: There were no treatment failures!

### **Conclusion**

All three human studies were deemed to be full treatment successes. A total of 41 Malaria patients were studied in the three human studies. There were no treatment failures in the studies. All participating patients were deemed to have achieved full recovered from the Malaria disease in averages of 4.5 to 6.5 days, with the theorized difference being the amount of product given daily in treatment. Specifically, the patients in test number two required an additional one to two days to achieve full recovery, but only about half the dosage was used in test number two as compared to test number one and three (15ml compared to 30ml in total daily usage).

# **APPENDIX 10**

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460</p> <p><b>NOTICE OF PESTICIDE:</b>  <input checked="" type="checkbox"/> Registration  <input type="checkbox"/> Re-registration</p> <p>(under FIFRA, as amended)</p>	<p>EPA Reg. Number: <b>73499-2</b></p>	<p>Date of Issuance: <b>APR 23 2003</b></p>
	<p>Term of Issuance: <b>CONDITIONAL</b></p>	
	<p>Name of Pesticide Product: <b>"ASAP-AGX-32"</b></p>	
<p>Name and Address of Registrant (include ZIP code):  <b>American Biotech Labs, LLC          70 West Canyon Crest Road, Suite D          Alpine, UT 84004</b></p>		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/re-registered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is conditionally registered in accordance with FIFRA Section 3(c) (7) (F) provided that you:</p> <ol style="list-style-type: none"> <li>1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c) (5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4.</li> <li>2. Make the following labeling changes:             <ol style="list-style-type: none"> <li>a. Revise the EIA Registration Number to read, "EPA Reg. No. 73499-2".</li> </ol> </li> </ol>		
<p>Signature of Approving Official  <b>Marshall Swindell, Product Manager, Team 33,          Regulatory Management Branch I          Antimicrobials Division</b></p>	<p>Date: <b>APR 23 2003</b></p>	

# **APPENDIX 1 1**



# UNIVERSAL LABORATORIES

20 RESEARCH DRIVE  
HAMPTON, VIRGINIA 23666

TELEPHONE: (757) 865-0880  
FAX: (757) 865-8014  
TOLL FREE: 800-695-2162

ASAP-AGX-32 Silver Solution versus MRSA (Methicillin resistant *Staphylococcus aureus* compared to eight leading disinfectants:

<u>Disinfectant</u>	<u>% Effectiveness versus ASAP-AGX-32</u>	<u>Coefficient</u>	<u>Test Date</u>
Chlorine	97.8%	1.02 : 1	04/04/05
Chlorhexidine	22.2%	4.20 : 1	04/04/05
Oxidizer	66.7%	1.5 : 1	03/25/05
High ORP Water with 0.7874% ASAP-AGX-32	56.4%	1.8 : 1	03/21/05
Iodine Iodophor	78.0%	1.3 : 1	03/25/05
Phenol	40.0%	2.5 : 1	11/25/04
Alcohol	17.8%	5.6 : 1	03/21/05
Quaternary Ammonium	1.3%	75.0 : 1	03/25/05
Aldehyde	0.9%	112.5 : 1	03/25/05



# **APPENDIX 12**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

August 04, 2004

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

AMERICAN BIOTECH LABS  
C/O KELLER & HECKMAN LLP  
1001 G STREET  
SUITE 500W  
WASHINGTON, DC 20001  
ATTN: FREDERICK A. STEARNS

510(k) Number: K042106  
Received: 04-AUG-2004  
Product: AGX SILGEL WOUND  
DRESSING

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/ocufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/oda/a02-01.html](http://www.fda.gov/cdrh/oda/a02-01.html).

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmmain.html> or me at (301) 594-1190.

Sincerely yours,



Marjorie Shulman  
Supervisory Consumer Safety Officer  
Office of Device Evaluation  
Center for Devices and Radiological Health

# **APPENDIX 13**

*John A. Shaw, M.D., P.C.*

10386 N. 96<sup>th</sup> Place  
Scottsdale, Arizona. 85258



Phone:  
Hospital (602) 285-3170  
Home (602) 998-7079

The recent availability of AGTX-32 Silvagel with silver at 32 parts per million in gel form has made it possible for us to treat an extremely common side effect of radiation therapy in treating breast cancer patients. Virtually 90 to 95% of the patients will have some degree of skin reaction from treatment of their breast cancer with external beam radiation. Over the years we have used a number of things very effectively in reducing this skin reaction with the most common agents being used are Kernalog 0.1% cream, Silvadene cream and Aloe Vera. All of these have done a fairly good job in assisting healing of the skin. However, we have now used the AGX-32 Silvagel in a number of these patients to promote healing. We have found that the AGX-32 Silvagel actually not only accelerates the healing process but actually will provide moisture to the dry damaged tissues in the patients who have dry desquamation and will absorb moisture from those that have too much moisture from weeping of the skin reaction.

Because of the effectiveness of the Silvagel in promoting the healing of the patients skin reaction, we are initiating a protocol wherein we will utilize the Silvagel on one half of the breast and use the Kenalog cream or Silvadine or Aloe Vera on the other half thereby providing the patient with their own control system. Pictures of the healing process will be taken on Day 1, Day 4, Day 7, Day 10 and Day 14.

It appears that from these earlier studies that the use of AGX-32 Silvagel will be an excellent tool in our armamentarium in promoting healing of the skin reaction from radiation therapy in the breast cancer patient.

  
John A. Shaw, M.D.

JAS/dc

# **APPENDIX 14**

ORRIN G. HATCH  
UTAH

PATRICIA KNIGHT  
CHIEF OF STAFF

101 Hart Senate Office Building

Telephone: (202) 224-8251  
TDD (202) 224-2848  
Fax: (202) 224-4331

Website: <http://www.senate.gov/~orin>

## United States Senate

WASHINGTON, DC 20510-4402

October 10, 2004

### COMMITTEES:

JUDICIARY  
CHAIRMAN

FINANCE

INTELLIGENCE

INDIAN AFFAIRS

AGING

JOINT COMMITTEE  
ON TAXATION

The Honorable Tom Ridge  
Secretary of Homeland Security  
3801 Nebraska Avenue  
Washington, DC 20528

Dear Mr. Secretary:

While the Department of Homeland Security continues to implement its plan to protect our nation and properly train and equip our first responders, I would like to bring to your attention the products provided by a Utah-based firm, American Biotech Labs.

American Biotech Labs has developed a disinfectant, known by its commercial name ASAP-AGX-32, whose test results have reportedly shown it to be an effective neutralizing agent against anthrax and other biological agents. Significantly, the manufacturer believes that though the disinfectant contains silver, the concentration of silver in the disinfectant is small enough that moderate human exposure is not typically harmful. However, chronic long term ingestion of silver or silver salts may cause argyria and is detrimental to aquatic life.

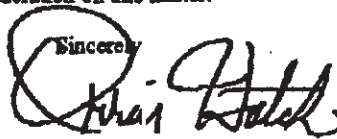
Despite this caution, the manufacturer believes that their disinfectant would not cause the same symptoms as a far more toxic disinfectant currently utilized by many first responders. American Biotech Labs used the compelling hypothetical example of an anthrax incident in a heavily populated area and the ability of first responders to disinfect that area immediately upon arrival rather than waiting until the area was clear so that the public would not succumb to the effects of the more toxic disinfectant.

It should also be noted that American Biotech Labs is working closely with WellPort Trinity on the development and utilization of this disinfectant. As you know, WellPort Trinity is a non-profit organization committed to building strong communities by bridging gaps in healthcare, childcare, education and affordable housing for the working poor.

Therefore, I respectfully request, as the Department of Homeland Security continues its work on the evaluation of equipment for first responders, that the Department evaluate and test American Biotech Labs's ASAP-AGX-32 disinfectant.

Thank you for your consideration on this matter.

Sincerely,



Orrin G. Hatch  
United States Senator

OGH:wcc



The Texas A&M University System Health Science Center

Office of Homeland Security  
John B. Connally Building  
301 Tarrow Street, 7<sup>th</sup> Floor  
College Station, TX 77840-7896  
979 458-7246 • fax 979 458-7202

~~CONFIDENTIAL~~

November 10, 2003

U.S. Department of Homeland Security  
The Honorable Tom Ridge, Secretary of Homeland Security  
Washington, D.C. 20528

Dear Secretary Ridge:

I would like to bring to your attention a resource that I feel can be utilized in the area of bio-defense from bio-terrorism to infectious diseases such as SARS.

The resource in question is the Anti-Microbial solution developed by American Biotech Labs in Utah. The ABL Anti-Microbial has undergone rigorous testing and has been found to kill Anthrax, Bubonic Plague, Hospital Staph, and SARS. It is the first new anti-microbial for the hospital in many years!

In addition, the ABL product is non-toxic to humans, EPA Approved (Hospital Staph & Bubonic Plague), and currently awaiting Sec 18 approval (Anthrax).

ABL's solution has shown to be a proven wide-spectrum anti-microbial/bio-decontaminant - that can be used to increase the safety and functionality of healthcare facilities in the event of a bio-terror attack or infectious disease outbreak such as SARS.

In short, we currently do not have anything with such a wide spectrum of efficacy as ABL Anti-Microbial in our inventory.

It should also be noted that ABL provides a dual use for the taxpayer because ABL is working with a faith-based organization that provides healthcare services to the working poor, and plans to train over 100,000 community volunteer first responders.

As such, I recommend that the ABL Anti-Microbial be evaluated for addition to the National Push-pack stockpile.

It will make our nation a safer place to live and work!

Respectfully,

A handwritten signature in cursive script that reads "Paul K. Carlton, Jr.".

Paul K. Carlton, Jr., M.D., FACS  
Lt. General, USAF (Ret.)  
Director, Integrative Center for Homeland Security  
Texas A&M University & Health Science Center

Cc: Senator Orrin Hatch  
Senator William H. Frist, M.D.  
The Honorable Tommy G. Thompson, Secretary of Health and Human Services  
The Honorable Anthony J. Principi, Secretary of Veterans Affairs  
Dr. Richard Carmona, United States Surgeon General

# ASAP vs. ACT For The Treatment Of Malaria

Thank you, Chairman Smith, for asking me to compare ABL's engineered, metallic silver nano-sized particles in water (e.g. ASAP 10), with artemisinin-based combination therapies (ACT's) for the treatment of malaria. While ASAP and the ACT's have a few similarities, the ACT's differ in a number of significant ways from ASAP, and depending on the circumstances, ASAP may be far more useful for a variety of public health, medical and humanitarian efforts at home and abroad.

ASAP and artemisinin are similar in that they both have their origins in the traditional medical practices of ancient cultures. Silver was used for its inherent anti-microbial properties by the ancient Egyptians and in the Ayurvedic medicine of India for thousands of years. Artemisinin is a derivative of an ancient Chinese herbal remedy for fevers - a plant called sweet wormwood - and likewise has been used for thousands of years<sup>1</sup>.

The raw materials from which ASAP is derived are water and silver, both in abundant supply in the US. ABL has access, through Clifton Mining alone, to 33 square miles of mines, representing several million ounces of silver reserves. ABL and Clifton collectively possess the skills and resources needed to produce ASAP from the ground up, without needing to consider implications of foreign trade policies, political instabilities, or interruptions to the flow of raw materials. The basic raw material for the production of artemisinin, on the other hand, is the sweet wormwood plant grown primarily in China and Viet Nam<sup>2</sup>. Production of the ACT's is thus dependent on the supply of sweet wormwood from these countries, and is vulnerable to interruptions in supply of the plant, crop failures, etc. Raw material supply problems have already caused interruptions in the anticipated supply of some ACT's<sup>3</sup>.

Once produced, ASAP has a shelf life estimated to be ten (10) years or more. This allows for the storage and stock-piling of ASAP on a large-scale basis. With an increase in production facilities, lead time is not an issue with ASAP. The ACT's and artemisinin on the other hand, have a shelf life of only 2 to 3 years. Long term stock-piling of the ACT's cannot take place and further, the shorter half-life of the ACT's creates the need for strict control of the supply chain to avoid stock outs, waste or improper use<sup>4</sup>.

ASAP is a broad spectrum anti-microbial with demonstrated effects against a wide variety of organisms including *B. subtilis* (a surrogate for Anthrax testing), numerous Staphylococcus species (including "flesh eating bacteria"), *E. coli*, Salmonella, bovine tuberculosis (a surrogate for human tuberculosis testing), and various fungi and viruses. ASAP has also been used in the treatment of both complicated and uncomplicated malaria and after traditional antimalarial drugs failed, even in babies as previously described. The broad spectrum of ASAP makes it an ideal agent for a variety of anti-microbial uses, providing almost unparalleled flexibility for health care planning and logistics. The ACT's, however, are indicated only for the treatment of malaria (and in some instances only for the treatment, for example, of uncomplicated falciparum malaria) and cannot be stock-piled for other alternative uses.

---

<sup>1</sup> The Journal of the American Botanical Council, HerbalGram, 2004; 64:19-20

<sup>2</sup> "The Use of Artemisinin & its Derivatives as Anti-Malarial Drugs", World Health Organization, WHO/MAL/98/1086

<sup>3</sup> "Update on world antimalarial drug supply", World Health Organization, Roll Back Malaria Department; Nov. 8, 2004.

<sup>4</sup> "Procurement of Artemether-Lumefantrine (Coartem®) Through WHO", World Health Organization, Roll Back Malaria Department.



Once administered, ASAP's engineered, metallic silver nano-sized particles function as single agent, medicinal catalysts with no known side effects. ACT's conversely, are, by definition, combination therapies and use two or more anti-malarial agents at the same time, many of which cause side effects in up to 40% of patients such as dizziness, headache, abdominal pain, loss of appetite, nausea, vomiting, or diarrhea<sup>4</sup>.

While the cure rates at 14 days are similar<sup>5</sup> for ASAP (100%) and the best of the recently tested ACT's (artemether-lumefantrine at 99%, with amodiaquine - artesunate a distant second at 89%), the higher incidence of side effects with ACT's may significantly impact their use as prophylactics against malaria. Based on available clinical data, it is anticipated that small daily doses of ASAP can be taken long term without side effects for malaria prophylaxis. Currently, travelers and residents in high risk malaria areas rarely use traditional or ACT long term prophylaxis, mainly due to the side effects and complications from the anti-malarial drugs<sup>6</sup>.

Much time and attention has already gone into assessing the affordability and financing of ACT's<sup>7</sup>. The costs of various ACT antimalarial options range from \$2.30 to \$3.60 per adult treatment and it is anticipated that ACT's are likely to have affordability and pricing problems<sup>7</sup>. Antimalarial treatment costs are a huge burden to countries where malaria is endemic and many African counties spend about one third of their health budget on this single disease.

On the brighter side, current pricing for ASAP is about \$2.50 per adult treatment and it is anticipated that there will not be affordability or pricing issues in regards to ASAP, especially for humanitarian efforts such as the treatment of malaria. In addition to the likelihood that the cost of an adult ASAP treatment for malaria is apt to decline as ABL's production and distribution capabilities increase and expand, ASAP is also a broad spectrum anti-microbial and thus burdened nations utilizing this option would no longer find themselves dedicating a significant portion of their health care budgets to a single disease.

Overall, while there are a few similarities between ASAP and the ACT's, the differences between the two make ASAP a viable and realistic adjunct, or even alternative, to the ACT's in the fight against malaria. The ACT's have potential raw material supply problems, have a comparatively short shelf life, are narrow in anti-microbial spectrum, have side effects both during treatment of malarial fever and as prophylaxis, and require dedication of a significant portion of the health care budgets of stricken countries to this single disease, thereby limiting the growth and flexibility of many developing nations.

As a recent addition to the health care armamentarium, ASAP provides another alternative that was previously unavailable. There is an abundant supply of raw materials for ASAP, it has a longer shelf life and is very broad spectrum (having been tested against malaria as well as a variety of other organisms including bacteria, viruses, and fungi). These characteristics make ASAP ideal for stock-piling as a general anti-microbial agent. ASAP has no known side effects and thus far has been well tolerated even in the critically ill, very young, and elderly. It is likely that the price of ASAP for malaria relief efforts will come down as ABL expands its production capabilities and strategic alliances. ASAP and other similar ABL products represent a new alternative for developed and developing nations alike, for improved health and wellness as well as treatment of many diseases.

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<sup>5</sup> Lancet, 2005;365:1439, 1474-1441, 1481-1483, 1487-1498

<sup>6</sup> "Coartem<sup>®</sup> Monograph", 3rd Edition January 04, Novartis.

<sup>7</sup> "Improving the Affordability and Financing of Artemisinin-Based Combination Therapies", Malaria Control Department & Essential Drugs and Medicines Policy Department, World Health Organization, WHO/CDS/MAL/2003.1095.