



DEVELOPING SCIENCE INTRODUCING TECHNOLOGIES

## You First Services Updates

You First Services, Inc., has been making steady and continuous progress following the commercialization of various products. There are several reasons for this steady growth. We have made corporate responsibility an integral part of our larger corporate strategy across the organization. Responsible business and a sense of personal responsibility is something that we want to establish across the company at all levels. With the marketing clearance from FDA and corresponding authorities from each county, YFS began to promote and market Lubricity® in the United States, Canada, European Union, India etc. It has increased the number of full-time employees from 2 in June 2015 to 14 as of June, 2017. The regulatory team works diligently to meet FDA guidelines and related approvals. The company has shown steady growth in development of multiple technologies in the field of oral health care, sterilization and infection control technologies. Our success will depend on our ability to successfully commercialize our product pipeline. With a team of world class scientific researchers and collaborators, YFS is committed to bring in solutions to many medical issues of concern.

YFS continues to recruit college and high school students for paid internships to its different divisions such as research, regulatory etc. from University at Buffalo Career fairs and partnering with other local agencies. This greatly helps students to advance their career

prospects. Many are subsequently being hired.

## Governor Cuomo Announces Expansion of YFS Pharma in Western New York

You First Services is excited to announce that Empire State Development of NY will assist the company with \$500,000 by including YFS Pharma in Excelsior



Job Program tax credits. Announcing this Governor Cuomo said "Western New York is rapidly becoming a hub of high-tech manufacturing with businesses choosing to come here and grow and expand in this region. With the addition of 28 new highly skilled jobs at YFS Pharma, we take another step forward to help grow the Buffalo area's economy – allowing this region to continue to thrive for years to come." According to Dr. Satish Sharma, Executive Chairman, You First Services Group of Companies "It is the vision of YFS to be a world-class research and development company. We remain committed to developing science and creating global partnerships. These partnerships with like-minded organizations will result in the introduction of unique health care

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applications that will contribute to decreased health care costs. The company aims to be a global leader in providing innovative health care technologies, and contribute significantly towards social advancement."

YFS Pharma one of You First Group subsidiaries will expand its operations in Western NY by setting up a pharmaceutical manufacturing facility. The project at YFS Pharma, Inc. involves the construction of a 9,467 square foot facility will allow YFS

Pharma to manufacture products for commercial sale and clinical trials. The CGMP and FDA certified facility will be located at 485 Cayuga Road, Buffalo, NY, 14225. This is in addition to 6,834 square feet of office space currently being leased in the same facility. This will create 28 additional jobs.

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## BIOFILMS—Their Important Architecture



**Robert E. Baier**

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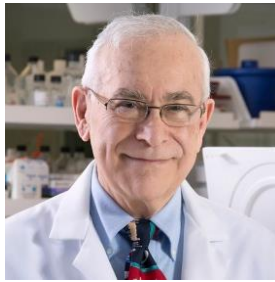
Dental plaque has been noticed for all of the known history of creatures with teeth, and slimes on ship bottoms have always been noticed since the first watery travels. About 50 years ago, a Canadian researcher named William Costerton (recently deceased) noticed similar slime on the rocks beneath a mountain stream—and chose to call it a “BIOFILM”. The term caught on, and was further popularized for medical product inserts (hips, knees, shoulders, more) by shoulder surgeon Anthony Gristina (also some years ago, departed). Waste water treatment operators encourage BIOFILM formation and persistence to clean flows about to re-enter the environment. “May you die with clean teeth!” was an Old Testament curse for starvation-induced removal of the person’s dental plaque, the original BIOFILM.

Surprisingly, even in cases where there were NO bacteria to make the BIOFILMS, it was seen that surface “scums” were routinely formed and often troublesome—such as in the red/yellow/whitish slimes found on the sterile surfaces of operated heart-lung machines and artificial kidneys. These thin films, and soon all other layers deposited by biology, became lumped into the general BIOFILM category. SO, it becomes important to know that all BIOFILMS are not the same and many do not cause infections (although triggering of blood clotting is often taken to be a similarly bad –or good-- result), even when building up to thicker layers such as those causing increased drag on commercial ships. Research addresses ways to overcome or eliminate the infectious BIOFILMS, since these are what trigger urinary catheter-based infections, and to remove blood deposits since these choke off patients’ medicinal and sampling lines. Some research seeks to actually promote BIOFILM formation, as in deliberately triggering blood clots to close off dangerous brain aneurysms!

Here is the important news: ALL BIOFILMS have common architectures, and this knowledge can both influence and often allow control of the film-forming processes and resistance to removal. First and absolutely required is the spontaneous displacement of water from a material’s surface and its replacement by a thin protein layer from the stream (slow in “clean” waters and very fast in blood and milk; a bit longer in saliva or tear fluid) less than a millionth of an inch thick. This becomes the “glue”, stronger or weaker depending upon what surface it first sticks to, that attaches (and retains, or not) the first arriving particles that you can actually see through a microscope. Bacteria are in this category, and so were called by the earliest microscopists, the “primary film” to distinguish it from any preceding layer of protein—now called the “conditioning film”—that was not yet visible to them. In the case of blood flow over a surface, the “primary film” particles are blood platelets (small disc-shaped particles) that attach to a fibrinogen (blood protein) “conditioning film” within the first minute of contact. ONLY then does an actual BIOFILM form, thickening to an easily seen and often infective layer of small particles that trigger further formations of slimy layers around and above them: a matrix of slimy, sugary material is secreted by the bacteria themselves or a matrix of fibrin protein catches passing red blood cells to give clots their red colors. Other layers occur in other systems, depending upon what is there in the first place. Often, mineralization can occur at the same time, such as the formation of “milkstone” on the hot walls of pasteurizers.

Control of BIOFILMS depends, absolutely then, on being able to get through the thickening matrix to the actual interface where the “primary film” particles are settled into a protected, usually bioactive zone resistant to slowly entering disinfectants or antibiotics that are “lost” on the way through the absorbing matrix gels. An approach that coagulates and disperses away the matrix first does render BIOFILMS more susceptible to eradication.

## NANOMEDICINE: What is it?



**Stanley Schwartz, MD, PhD.**

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Nano means one billionth and a nanometer is one billionth of a meter. For comparative purposes if a nanoparticle were to grow to the size of football then a donut would grow to the size of New Zealand. Nanoparticles used in nanomedicine generally range in size between 10 to 100 nanometers. Nanotechnology is the science and engineering involved in the characterization, application and manipulation of materials and devices at the atomic or molecular size range. Nanomedicine is defined as the application of nanotechnology to the practice of medicine. Nanomedicine can be used for the prevention, diagnosis and treatment of many different diseases. Nanoparticles are being used in medicine to carry treatments including drugs and genes to specific cells such as cancer or infected cells or specific tissues and organs such as the brain. In addition to carrying treatments, nanoparticles can protect therapeutic drugs and genes from rapid degradation by the body thus prolonging their beneficial effects.

Some drugs like cancer chemotherapy can be toxic to normal cells and tissues. By concentrating toxic drugs within nanoparticles and targeting them to specific cells, nanoparticles can reduce their detrimental side effects. Nanoparticles have the ability to deliver large payloads. Thus in addition to carrying drugs they can also carry agents that can visualize the target tissues making it easier to see them on imaging techniques such as magnetic resonance imaging (MRI). This property of “treating and seeing” has been termed theranostics from **therapy** and **diagnostics**. The emerging concept of personalized or precision medicine wherein therapies are specifically tailor made for individual patients based upon their unique genetic makeup is readily using techniques from nanomedicine. The following are some examples of ongoing developments in nanomedicine. Diseases of the brain are notoriously difficult to treat because a natural, protective “blood-brain barrier” prevents foreign materials, including treatments, from moving from the blood into the brain. Nanoparticles can safely pass through the blood-brain barrier and carry treatments to the brain. Replacing abnormal genes with normal ones, gene therapy, suffers the problem that genetic therapies, DNA and RNA, can be rapidly degraded when given orally or intravenously. Encapsulating these nucleic acids in protective nanoparticles which travel to target tissues and slowly release their contents significantly improves the feasibility of gene therapy. Nanoparticles are being used to deliver natural plant products often used as health foods as safe treatments for cancer and neurological diseases. One last example is the use of nanoparticles to hunt down and treat multiple dispersed metastases of malignant tumors. We are entering a new era of nanomedicine where the impossible is becoming possible. The Buffalo Niagara Medical Corridor has become a source of many exciting developments in nanomedicine research and development. Stay tuned for further advances in nanomedicine.



## Uses of Plasma in Priming and Disinfection



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Plasma is the “4<sup>th</sup> state of matter”, as in solid, liquid, gas, and plasma. It is created naturally in the ionosphere (for example the Auroua Borealis or northern lights), and can be prepared artificially inside a vacuum at low pressure. When a controlled recipe of electro-magnetic energy is supplied to a gas by varying an electrical current, the gas becomes electrically conductive and ionized. Ionization occurs when electrons are stripped from gaseous molecules as a result of the applied electro-magnetic field. The emission of light or the plasma “glow” results naturally from energized electrons becoming de-energized and emitting photons. An artificial plasma has a partial ionization meaning that only a fraction of the molecules are ionized. The amount of electrons stripped from the gas molecules is the “electron density” or how many electrons are present in a given volume of space inside the plasma. The cascade of energetic particles, electrons and ions, are utilized by professionals in industry and medicine to perform favorable preparations to both solid materials and also gases. Simply put, plasmas are used to 1) modify or activate the surface chemical properties of a material, 2) create a new material, 3) clean and remove surface residue, 4) disinfect or sterilize a material that is harbors microbiological contamination, and 5) detoxify constituents suspended in the gas stream. Plasma devices are very well known by professionals in the laboratory who use them to prepare samples. The electronics and computer industry also prepare semi-conductors and computer chips in a plasma.



To understand how a plasma can be used, we must first mention surface science and look at the surface chemistry of a solid material. The outermost atomic layers of all solid materials display unique properties depending on the chemistry of the specific material. For example, a piece of clean and residue-free stainless steel, glass, or ceramic typically has a high surface energy and such a surface can easily accept a coating of adhesive, glue, or paint. In contrast most polymers including polypropylene (PP), polytetrafluoroethylene (PTFE), polyetheretherketone (PEEK), silicone, paraffin waxes, and acetal (POM) cannot be bonded to easily. If a naturally occurring low-surface-energy plastic material is treated inside a gas plasma, the surface energy and critical surface tension becomes substantially increased. Vacuum plasma treatment of Teflon® has been widely adopted in the medical industry for printing and gluing operations in catheter manufacturing, where a the fluorocarbon surface is modified to produce a permanent change in surface energy (critical surface tension) from 18 dynes per cm to more than 70 dynes per cm. Plasmas afford an effective surface activation or pre-treatment prior to gluing, printing, or lacquering with a coating. Glass and ceramics are easy to plasma activate. Another example of applying a plasma to a practical process treatment is the removal of organic compounds (oil residue) from a surface with an oxygen gas plasma. Plasmas are routinely used to clean and surface-treat plastic automotive parts, performance textiles and filter media, stainless steel syringe needles, angioplasty balloon catheters, plastic lenses, golf balls, and many other diverse products. Mild plasma source is ideal for treatments to hard surfaces used in industry, for instance removing thin films and residue, surface bonding and adhesion improvements for gluing two surfaces or surface coating applications. The system is useful in the electronics industry before soldering, after drilling, or before adhesion of micro-circuits. Plasma treatment promotes adhesion and enhances bonding to other surfaces or applied coatings.

However, the benefits of plasma treatment is less known in medicine. Plasma can be used as disinfectors and sterilizers to be used in clinical applications for killing micro-organisms on medical devices (Blood Pressure Cuffs, Stethoscopes, Pulse oximeters, Ultrasound Probes & Transducers, Otoscope/Ophthalmoscopes, and plastic endoscopes). It can be uses very effectively in the sterilization of heat sensitive expensive modern complex medical devices. Other new emerging product applications, in agriculture cold vacuum plasmas have been shown to enhance oilseed rapeseed germination under drought stress conditions. Cold radiofrequency vacuum plasma is capable of improving the speed of germination to facilitate more rapid growth of crops. Cold radiofrequency plasma treatment increases germination speed of plant seeds as a direct result of wettability improvements with water and plant nutrients. .

## Our Success

## Product Updates

You First Services continues to develop products which are useful to the masses.

## GloTran™

The plasma cleaner/Disinfector, GloTran™, successfully cleared all compliance and electronic safety testing and is ready for the market as an industrial device. Laboratory validation for the disinfection capabilities are undergoing now. It is capable of rapid, automatic, low to mid-level disinfection of non-critical patient contact devices and instruments. This prevents the spread of hospital acquired infections (HAIs) from routine patient to patient contact by the devices



The GloTran® model GT-11 System is a new low-temperature cleaner and disinfector that was recently tested by Underwriters Laboratory for laboratory electrical equipment safety. The certification of UL 61010-1 is for safety and safe operation of electrical medical equipment for Measurement, Control, and Laboratory Use. The Underwriters Laboratory determined that the new product complies with the UL 61010-1

standard which is required for commercial sale in United States and Canada. The equipment was also evaluated per IEC/EN 61010-2-240 which defines “particular requirements for sterilizers and washer-disinfectors used to treat medical materials”. GloTran™ also complies with this sub-set of the standard as it pertains to the electrical and mechanical areas required for receiving FDA clearance of this product as a sterilizer.

The GloTran® is an automatic surface cleaning machine that has



enormous potential also as a broad spectrum antimicrobial process with applications in medical, and industrial settings (e.g. decontamination of medical instruments). A major advantage is the shallow penetration of the gas plasma: only ~10-20 nm from the surface thereby minimizing damage to the material being treated. It is especially useful for cleaning and disinfecting heat and moisture sensitive thermoplastic articles. This an ecofriendly, non-contact dry cleaning process and substitute for wet chemical processing of items with no hazardous liquid byproducts requiring waste disposal.

Routine use and handling of reusable devices in the clinic results in contamination of other surfaces. These undesirable contaminants are typically of organic and inorganic origin, and are both viable and non-viable in nature. If not addressed between patient uses, the presence of these contaminants can hinder the clinician’s ability to

provide safe and effective medical care.

The new product was developed to provide clinician’s additional methods to prevent infections spread from intimate devices

The GloTran® is designed for rapid, automatic, low to mid-level disinfection of non-critical patient contact devices and instruments. This prevents the spread of hospital acquired infections (HAIs) from routine patient to patient contact by the device.

## MetaQil™



You First Services continues to bring valuable oral care products to help the people suffering from different health conditions. The latest in the series is MetaQil™ ([www.metaqil.com](http://www.metaqil.com)) an oral rinse which can alleviate metallic taste in the mouth caused by treatment of cancer or various prescription drugs. It is launched in to the market as a convenient to carry and easy to use 2 oz bottle. Further, MetaQil™ is being evaluated for its efficacy in comforting metallic taste at the School of Dental Medicine, University at Buffalo.

### Lubricity®

You First Services, Inc. is excited to announce that the Food and Drug Administration (FDA) has cleared the 510(k) premarket notification (K163476) application for Lubricity® with device classification category as Artificial Saliva and product classification code LFD (for the relief of chronic and temporary xerostomia). This premarket notification clearance will enable Lubricity Innovations, Inc. to market Lubricity® as a medical device. With the marketing clearance from FDA and corresponding authorities from each country, YFS began to promote and market Lubricity® in the United States, Canada, European Union, India etc. Lubricity® continues to be widely appreciated by people suffering from dry mouth and is being evaluated for its efficacy in dry mouth caused by various conditions through clinical studies. The studies are at different stages in the progress



### YFS Pharma included in NY State Excelsior Job Program

**The Excelsior Jobs Program encourages businesses to expand in and relocate to New York while maintaining strict accountability standards to guarantee that businesses deliver on job and investment commitments. This program provides job creation and investment incentives to firms in such targeted industries such as biotechnology, pharmaceutical, high-tech, clean-technology, green technology, financial services, agriculture and manufacturing.**

### YFS Pharma

You First Services, Inc will be launching its own manufacturing company, YFS Pharma, scheduled for small-scale implementation by Fall of 2017. YFS Pharma will be making its own oral care products Lubricity, Swish4 and MetaQil etc onsite in the very near future. It will start small-scale (maximum 1000 units/day) with the intent to go large-scale (over 1000 units/day) by 2018. This development is of great value and profit to YFS Pharma and signifies growth in the market. This is an exciting opportunity for all staff to be part of the set-up of a new manufacturing facility and QC lab from the start.

Before one can celebrate the production success, much needs to be done to pave the way to the launch of operations. Running our own manufacturing and QC Lab is a highly-regulated endeavor. Aside from the logistics of building the space, purchasing equipment for both production and lab, purchasing raw materials to make the products, hiring and training staff, a good amount of ensuring our new facility is to code and our products are safe before operations start and on an ongoing basis needs to be accomplished as well as become part of our culture and mindset.

To ensure all process are to code and safe, the company will be adhering to the GMP (Good Manufacturing Practices) which is governed by the FDA (Food and Drug Administration) and OSHA (Organization for Safety and Health Organization) guidelines. The FDA is the agency auditing these production facilities every two years. These visits are unannounced yet generally fall within the same quarterly to six-month schedule; however, this is not a steadfast rule. Protocols for external audits will need to be put into place to facilitate an awareness of the audit-procedure for all and a structured, confident experience for those involved directly with the audit-process. OSHA guidelines will be adopted to ensure compliance with health and safety which go hand and hand with FDA standards. With defined processes and policies to date, it can be assured YFS Pharma will be a safe environment producing quality product as well as being fully compliant with regulatory agencies.

### Clinical Studies

#### METALLIC TASTE

Subjects taking chemotherapeutic agents often do not comply well with their dosing regimen since many of these medications cause a metallic taste in the mouth. This study undergoing in the School of Dental Medicine, University at Buffalo under Dr. Sebastian Ciancio, Distinguished Professor and Chair of Department of Periodontics has two key objectives. The primary intent is to determine the effectiveness of Metaqil™ oral rinse in reducing the metallic taste in the mouth associated with various chemotherapeutic agents. This study will also confirm that the test formulation is safe for daily use in home oral care over a one-month treatment period

#### DRY MOUTH IN SLEEP APNEA

Patients suffering from obstructive sleep apnea (OSA) often wake up with a dry mouth during the night or in the morning and impacts quality of life. As patients with OSA spend most of their sleep time desperately seeking for air, it is not surprising that they wake up with a dry mouth, as the instinctive physiological response is to open the mouth to allow as much air in as possible. Saliva has important functions in protecting the hard and soft tissues of the oral cavity from acids and pathogenic microbes.

The HA formulation designed to alleviate dry mouth in these OSA patients undergoing clinical study to determine its efficacy. This cross-over group, randomized, study enrolls subjects from the sleep clinic of Veterans Administration (VA) Hospital of WNY under the IRB approved protocol. The product is expected to be released in to the market shortly.

#### DRY SKIN TREATMENT

The clinical study to test the ability of an HA formulation to minimize the problems caused by dry skin due to various reasons is approved by the IRB and the study will start soon. This randomized study will investigate the tolerability of a novel lubricating solution in patients with symptomatic skin dryness and its efficacy in minimizing the symptoms associated with dry skin.

#### XEROSTOMIA TREATMENT

Results of the Lubricity clinical study titled "Efficacy of an Intra Oral Spray for Patients With Xerostomia" was presented at the 95th Annual meeting of The International Association for Dental Research (IADR) and it was well received in the dental research community. Abstract can be accessed using the hyperlink given below. <https://iadr2017.zerista.com/event/member/329957>

WELCOME NEW EMPLOYEES

Collaborators

Sandeep Dhindsa, M.D.



Kris Johnson

MARKETING DIRECTOR



Latashia Booze

PROGRAM COORDINATOR



Dr. Sandeep Dhindsa completed his medical schooling from All India Institute of Medical Sciences in New Delhi, India. He did a residency in Internal medicine from State University of New York at Brooklyn and fellowship in Endocrinology from State University of New York at Buffalo in 2002. Currently he is an Associate Professor of Medicine, Director, Division of Endocrinology and Metabolism, Saint Louis University, Saint Louis, O. His primary area of research is in the field of hypogonadism and type 2 diabetes. He has over 60 publications in peer-review journals. He is frequently invited to give talks and grand rounds on the topic of hypogonadism in men. He is a member



Archana Mishra, M.D.

Dr. Mishra is an Associate Professor of Clinical Medicine at the State University of New York at Buffalo. She completed her medical schooling from Rajendra Medical College and Hospital in Ranchi, India. Following this, she pursued her education in the United Kingdom and then moved to the United States. She completed her residency in Internal Medicine at Long Island College Hospital where she received the Best Resident award. Following this she completed her fellowship in Pulmonary, Critical Care, and Sleep Medicine at North Shore University Hospital in Manhasset, New York, where she received an education award in recognition for exceptional teaching.



YFS Foundation held their second annual charity dinner on April 21st, 2017 at the Transit Valley Country Club in East Amherst, NY. The event is to help support girl child education in developing countries, and also provided college scholarships to four local high school students pursuing scientific, medical and technological careers. Over 100 guests attended the event including Buffalo Public School Board Chairman Dr. Barbara Nevergold.



YFS Foundation is very glad to announce that it is continuing to collaborate with IIMPACT ([www.iimpact.org](http://www.iimpact.org)) a non-governmental organization in India whose primary focus is the education of girl children from socially and economically disadvantaged sections of society. This year YFS Foundation is planning to sponsor 200 girls including the 60 children it supported last year. In addition the Foundation is setting up libraries and computer rooms for the learning centers.

Any questions please contact:  
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