NASCENT SURGICAL, LLC™

To: **Ms. Julianne Sum, Chief** **31 October 2018**
Division of Occupational Safety and Health
Re: **Cal/OSHA Advisory Meeting**
Protection of Employees from Surgical Plume and Smoke
Thursday November 8, 2018 10 AM-3:00PM

From: Leonard Schultz, M.D.
Founder and Chairman
Nascent Surgical, LLC
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Dear Ms. Sum,

Let me begin by thanking the Standard's Board for recognizing the importance of protecting the health of the perioperative teams and their patients during surgical procedures by requiring capture of surgical smoke and bioaerosols. Finally, the danger of chronic inhalation of plume components, including nanoparticles ("ultrafine particles") and bioaerosols that contaminate surgical wounds is being taken serious

I believe that your deliberations leading to a Final Rule will be pivotal to the future well-being of hundreds of thousands of perioperative workers in our surgical facilities, both public and private. By providing a Rule based on a reasonable Standard, the panel can, coincidentally, not only protect the worker but also the responsible healthcare administration from unnecessary future workman

compensation claims that could dwarf the cost of mesothelioma-related claims stemming from toxic asbestos inhalation.

Panel members may be aware of my previous correspondence with the Board at the time of their consideration of Petition #567. In that letter, I argued for the need for universal application of the mandate because no one can know the degree of an individual's sensitivity to chronic inhalation of nanoparticle effects which are related to genetics, pre-existing illnesses and dose/duration of exposure to the contaminants. At this time, I ask your indulgence to consider my background in smoke exposure and methods of control followed by comments as they relate to the Draft of the "Occupational Exposure to Surgical Plume # 51XX.

I am a retired general surgeon with 30 years of operating room experience during which time I developed an interest in the use of lasers for the treatment of large cancerous tumors. As a result of the debulking of these masses with the carbon dioxide laser, the room filled up with smoke that could not be cleared with available suction. To speed the removal of the smoke, I helped the hospital engineers develop a central vacuum system called CVAC which was made by Spenser Turbine and distributed by Hereus Medical. In addition, I invented a disposable reticulated cell foam-based plenum which could collect smoke directly from the source by being attached to tubing, filtered with an ULPA filter and powered by a very noisy turbine, also called a "smoke evacuator." The smoke capture device was presented

at the April, 1989 meeting of the American Society of Laser Medicine and Surgery at which time it was noticed by Mr. Roger Barnes of the FDA which led to his fast track approval of the product for commercial use within 90 days through the 510(k) process. It was then put on a shelf in deference to my next product.

My other major surgical interest was laparoscopy which led to the first report of laparoscopic cholecystectomy at a professional meeting (American Society of Laser Medicine and Surgery) in April, 1989. This was followed by my report of the first laparoscopic hernia repair with mesh at the 1990 meeting of the American College of Surgery. The problem of how to simply remove the smoke that obscured the laparoscopic lens was solved when I introduced the first biphasic, passive filter (ULPA filter and activated charcoal filter in a casing) that was placed in-line to a stopcock vent attached to every laparoscopic trocar. This device, along with some 20 product-related patents was sold to Cooper Surgical, Inc. in December, 2009.

Soon thereafter, I again focused on removal of smoke that was produced in open surgical cases and resurrected the first product that was developed for that specific purpose. I and other investors formed Nascent Surgical, LLC, incorporated in Minnesota and spent the first four years perfecting its market acceptance. The original design got a reduced footprint and was renamed miniSquair® and has been sold for the past four years with ever-increasing interest while its competitive ESU "pencil" has met with surgeon resistance making compliance to

smoke evacuation policy an issue for hospital administrators. Our device is sold against various "pencil" variants made by companies such as Covidien, Stryker, Buffalo Filter, Conmed, etc.

Since we started, the Company has sponsored research that has advanced the basis for "Why smoke should be evacuated" and includes:

1. **First measurement of "% smoke capture efficiency" by the Particle Calibration Lab, Dept. of Mechanical Engineering, Univ. of Minnesota.**
2. **Determined that surgical smoke contained 80% nanoparticles and related chronic inhalation of same to serious systemic diseases, depending upon patient variables.**
3. **Capability of current technology to not only capture nanoparticles (98-99.5%) but airborne and droplet transmitted bioaerosols.as well.**
4. **Introduced the concept that effective capture of ambient wound bioaerosols should lead to a decrease in the rate of post-operative infections.**
5. **Initiated a study of over 1,300 posterior spinal fusion patients divided into equal groups with and without use of the miniSquair® with results showing a trend toward reduced infection rates when effective smoke evacuation technology was used. A "power analysis" indicates that a significant "p" value should come as the study is expanded. This study**

introduced the possibility that smoke evacuation could represent an adjunctive infection control device.

With this clinical and research experience to guide me, I would like to suggest the following to the Panel as they evaluate the "Discussion Draft for Occupational Exposure to Surgical Plume" which is scheduled for an advisory Meeting in Oakland, California this November 8, 2018:

51XX Occupational Exposure to Surgical Plume

a) Scope and Application. This section applies…psychiatric hospitals, special hospitals "and outpatient surgical facilities including surgeries done in private physician's offices

b) Definitions

(6) "Plume scavenging system" means smoke capture devices such as the ESU "pencils," "wands" and cell foam-based plenum devices inclusive of attached tubing, in-line ULPA filters and smoke evacuators...tract of employees."

(9) "surgical plume" means…(vapors, gases, bioaerosols and cellular debris")…electrosurgical devices.

(10) "Plume capture devices" means devices used to capture plume at its source and includes the "wand" which has 7/8th" I.D. of corrugated tubing or a rigid plastic segment with a mesh covering, the electrosurgical unit "pencil" or "pen" which is an electrode with an embedded or attached corrugated tubing of 3/8th" I.D.which is held by the surgeon

close to the smoke source and the cell foam-based plenum attached to 1 1/4" corrugated tubing placed but not held adjacent to the smoke source."

Control Measures.

(1) Engineering controls.

(A) Plume Scavenging Systems. "Exposure…generated." Its components include:

1. The capture device. It should be placed within 1" of the smoke source and tested by a 3rd party and documented to achieve a minimum smoke capture efficiency of 90%.

2. The conduit tubing should be at least 7/8th" I.D. corrugated tubing capable of moving a minimum of 25-35 cfm of air in order to achieve maximum smoke and bioaerosol capture.

3. ULPA filter to be tested by a 3rd party laboratory to ensure a minimum 99.99% capture of particulates down to 0.1um or 100nm in size.

4. The turbine smoke evacuator machine shall be capable of generating a maximum decibel level of no more than 40-45 db at maximal power and capable of moving a minimum of 25 cfm of air when tested with an acceptable smoke capture device, tubing of internal diameter as described above in A2 and an in-line ULPA filter as per A3.

This will protect human hearing and achieve maximum smoke capture.

DOCUMENTATION FOR THE ABOVE STANDARDS ARE TO BE PROVIDED BY THE MANUFACTURER OF ANY COMPONENT OF A "PLUME SCAVENGING SYSTEM."

Exception: There should be no exception since all elements should be FDA approved for safety and efficacy or show proof of product verification/validation through documentation.. Should any component need to be "…located further away from the site-of-origin" for safety reasons, then such component must be considered invalid for use in the "System."

(2) Administrative Controls, including work practices, shall be used when plume scavenging systems….extent feasible."

c). Resources on Occupational Exposure to Surgical Plume

PLEASE continue to include the reference for ISO 16571:2014, "Systems for evacuation of plume generated by medical devices." Especially note Section 4.3 which, for the first time, suggests an international standard for "percent (%) smoke capture efficiency" for plume removal which "…shall

be at least 90%... Evidence shall be provided by the manufacturer." Adoption of this studied standard will, I believe, best protect the short and long-term health of the worker.

Further, please consider the following reference which documents why surgical smoke MUST be captured effectively.

Buzea C, Blandino I I P, Robbie K. Nanomaterials and nanoparticles: Sources and toxicity. 2007. Biointerphases; 2(4): MR17-MR172.

Thank you for considering my comments as regards the forthcoming discussion on how best to protect the perioperative team from environmental pollution generated by the contaminants in surgical plume.

Sincerely yours,
Leonard Schultz, M.D.