IN THE SUPREME COURT OF THE STATE OF UTAH

Dale Burningham and Lana Burningham, Appellants, v. Wright Medical Group, Inc., and Wright Medical Technology, Inc., Appellees.	Appellate Case No. 20180143-SC

NOTICE OF APPELLANTS' SUPPLEMENTAL AUTHORITY PURSUANT TO UTAH RULE OF APPELLATE PROCEDURE 24(j)

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Appellants provide this Notice of Supplemental Authority ("Notice") pursuant to Utah Rule of Appellate Procedure 24(j). The supplemental authority comes in the form of under-oath regulatory opinions offered by Appellee Wright Medical Technology, Inc.'s ("Appellee") regulatory expert and former employee of the Food and Drug Administration ("FDA"), Stephen Rhodes, MSE. The testimony was obtained by undersigned counsel in another matter involving Appellee, *Applekamp et al. v. Wright Medical Technology, Inc.*, Case No. 17-CV-01601 (D. Colo.), involving the medical devices at issue in this matter. A copy of Appellee's F.R.C.P. 26(a)(2) Disclosure Certificate in the *Applekamp* matter, and Mr. Rhodes' *Curriculum Vitae*, are attached as **Exhibit A**.

The timing of this Notice stems from Appellee's recent agreement, on December 10, 2018, that the authority disclosed herein is not confidential pursuant to the governing Protective Order in the *Applekamp* matter. *See* correspondence from counsel for Appellee in the *Applekamp* matter, attached as **Exhibit B**.

The testimony and authority provided by Appellee's own retained-expert, relevant excerpts attached as **Exhibit C**, and references to Appellants' briefs to which the authority applies, are as follows:

(1) 510(k) clearance does not mean that the FDA has approved the safety and efficacy of the device in question. **Ex. C**, 46:19-22. *See also* Appellants' Opening Brief, pp. 3; 22-23.

(2) A device manufacturer may not advertise that 510(k) clearance represents FDA approval of the medical device in question. **Ex. C**, 46:23-47:4. *See also* Appellants' Opening Brief, p. 22; Appellants' Response Brief, p. 4.

(3) 510(k) clearance means that the FDA has determined that the medical device in question is substantially equivalent to a predicate device(s), whereas FDA approval

via the PMA process means that the FDA has evaluated the safety and effectiveness of the medical device in question and has confirmed that the device is safe and effective for its intended use. **Ex. C**, 47:8-48:1. *See also* Appellants' Opening Brief, pp. 10; 16-17; 27.

(4) Unlike PMA submissions, the overwhelming majority of 510(k) submissions do not include clinical data. **Ex. C**, 42:19-20; 43:4-9. *See also* Appellants' Response Brief, p. 5.

Respectfully submitted this 14th day of December 2018.

/s/ Thomas R. Leemon
Thomas R. Leemon
George E. McLaughlin
Brian C. Stewart
Attorneys for Appellants

Proof of Service

This is to certify that on the 14th day of December 2018, I caused to be mailed, first class, with the United States Postal Service, two (2) true and correct copies of the foregoing Appellants' Notice of Supplemental Authority Pursuant to Utah Rule of Appellate Procedure 24(j) to:

Elisabeth M. McOmber
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Attorneys for Appellees

/s/ Thomas R. Leemon
Thomas R. Leemon

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.: 1:17-cv-01601-CBS-WJM-MLC

SCOTT APPLEKAMP;
GAIL APPLEKAMP;

Plaintiffs,

v. -

WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation,

Defendant.

DEFENDANT WRIGHT MEDICAL TECHNOLOGY, INC.'S
F.R.C.P. 26(a)(2) EXPERT DISCLOSURES

Defendant Wright Medical Technology, Inc. ("Wright Medical"), by and through counsel, Howard & Howard and Childs McCune LLC, hereby submits their F.R.C.P. 26(a)(2) Expert Disclosures.

INTRODUCTION

Defendant's experts will be asked to testify concerning the nature of their work, their education, training, and experience as set forth in their *Curricula Vitae*, and experience concerning the issues in this case. Experts endorsed by Defendant may further be asked to provide opinion testimony based on their knowledge and review of practice standards and expectations, applicable literature, published treatises, periodicals, facts and data made known to them, and any other facts or data reasonably relied upon by experts in their field in forming opinions.

Defendant reserves the right to offer opinion testimony from these witnesses that is rendered during their depositions, if taken in this case, and Defendant reserves the right to propose hypothetical questions to these expert witnesses at trial and ask questions based upon evidence to be introduced at trial. Defendant reserves the right to have retained experts review and revise or modify their opinions based upon the deposition testimony of fact witnesses and experts, as well as newly provided facts, opinions, records, and/or materials. Defendant also reserves the right to have these experts answer, rebut or respond to the testimony and/or further opinions of Plaintiffs' experts, whether the opinions come from depositions, trial, supplemental reports or from other means.

Defendant's experts may further testify concerning any exhibit introduced during their depositions, if taken, and concerning any exhibit introduced at trial. These experts may further rebut the testimony of Plaintiffs' experts and may supplement their opinions as discovery progresses and as new evidence becomes available, including any rebuttal expert reports.

Any expert endorsed by Defendant may use some or all of the following to assist them in their testimony: deposition testimony, excerpts, time lines, enlargements of records, diagrams, graphs, and any other demonstrative exhibit or evidence to illustrate the expert's testimony.

This disclosure of expert testimony is based upon the information provided to Defendant, at this time. Defendant expressly reserves the right to supplement these expert disclosures with additional opinions and information as they become available.

A. RULE 26(a)(2)(B)(I) RETAINED EXPERTS

1. JAMES BONO, M.D.
New England Baptist Hospital
125 Parker Hill Ave., Suite 573
Boston, MA 02120
617-754-5901

A report prepared by Dr. Bono, which expresses his opinions on Plaintiff's claimed injuries and damages, accompanies this disclosure. Dr. Bono's background, training, qualifications and experience are reflected in his enclosed Curriculum Vitae at ***Exhibit A*** to his report. A list of his publications is included in his enclosed CV. Dr. Bono has testified as an expert in the last four years and a list of his prior testimony is enclosed with his report. His rate for record review is $1,000 an hour, and his rate for testimony is $7,500 per day. The list of materials Dr. Bono has reviewed are attached at ***Exhibit B*** to his report.

The facts or data considered by Dr. Bono in forming his opinions are identified in his report.

If called as a witness, Dr. Bono is expected to testify to those matters addressed in his accompanying report. It is anticipated that Dr. Bono will have additional opinions as additional information, records and evidence become available.

Dr. Bono will further testify regarding any and all relevant matters addressed in his deposition. Dr. Bono will further testify regarding any and all other matters raised by Plaintiff's experts that are within his area of expertise. Dr. Bono may supplement his opinions, as additional evidence becomes available. Dr. Bono may use diagrams and illustrations in support of his testimony, and he may use relevant documents from the case files, depositions, trial transcripts, or other discovery documents in support of his testimony. Dr. Bono may be asked to comment on any literature that is relevant to the issues in this case.

2. BRAD JAMES, PH.D., P.E.
Exponent Inc.-Principal Engineer
149 Commonwealth Dr.
Menlo Park, CA 94025
650-326-9400

A report prepared by Dr. James, which expresses his opinions in this matter, accompanies this disclosure. Dr. James' background, training, qualifications and experience are reflected in his Curriculum Vitae, which is included in his report at Appendix B. A list of Dr. James' publications is included in his CV. Dr. James has testified as an expert in the last four years and his list of prior testimony is included in his report at Appendix C. His rate for record review and testimony is $495.00 an hour.

The facts or data considered by Dr. James in forming of his opinions are identified in his report at Appendix D.

If called as a witness, Dr. James is expected to testify to those matters addressed in his accompanying report. It is anticipated that Dr. James will have additional opinions as additional information, records and evidence become available.

Dr. James will further testify regarding any and all relevant matters addressed in his deposition, if taken in this case. Dr. James will further testify regarding any and all other matters raised by Plaintiff's experts that are within his area of expertise. Dr. James may supplement his opinions, as additional evidence becomes available. Dr. James may use diagrams and illustrations in support of his testimony, and he may use relevant documents from the case files, depositions, trial transcripts, or other discovery documents in support of his testimony.
Dr. James may be asked to comment on any literature that is relevant to the issues in this case.

3. JORGE OCHOA, PH.D., P.E.
Exponent Inc. - Principal Engineer
149 Commonwealth Dr.
Menlo Park, CA 94025
650-326-9400

A report prepared by Dr. Ochoa, which expresses his opinions in this matter, accompanies this disclosure. Dr. Ochoa's background, training, qualifications and experience are reflected in his attached Curriculum Vitae, which is included in his report at Appendix B. A list of Dr. Ochoa's publications is included in his enclosed CV. Dr. Ochoa has testified as an expert in the last four years and his list of prior testimony is included in his report at Appendix C. His rate for record review and testimony is $490.00 an hour.

The facts or data considered by Dr. Ochoa in forming his opinion are identified in his report at Appendix D.

If called as a witness, Dr. Ochoa is expected to testify to those matters addressed in his accompanying report. It is anticipated that Dr. Ochoa will have additional opinions as additional information, records and evidence become available.

Dr. Ochoa will further testify regarding any and all relevant matters addressed in his deposition, if taken in this case. Dr. Ochoa will further testify regarding any and all other matters raised by Plaintiff's experts that are within his area of expertise. Dr. Ochoa may supplement his opinions, as additional evidence becomes available. Dr. Ochoa may use diagrams and illustrations in support of his testimony, and he may use relevant documents from the case files, depositions, trial transcripts, or other discovery documents in support of his testimony. Dr. Ochoa may be asked to comment on any literature that is relevant to the issues in this case.

4. STEPHEN RHODES, MSE

Biologics Consulting Group, Inc. - Senior Consultant
400 N. Washington Street, Suite 100
Alexandria, VA 22314
703-739-5695

A report prepared by Mr. Rhodes, which expresses his opinions in this matter, accompanies this disclosure. Mr. Rhodes' background, training, qualifications and experience are reflected in his attached Curriculum Vitae, listed as *Exhibit A* to his report. A list of Mr. Rhodes' publications is included in his enclosed CV. Mr. Rhodes has testified as an expert in the last four years and his list of prior testimony is included in his report. His rate for record review and testimony is $500.00 an hour.

The facts or data considered by Mr. Rhodes in forming his opinion are identified in his report.

If called as a witness, Mr. Rhodes is expected to testify to those matters addressed in his accompanying report. It is anticipated that Mr. Rhodes will have additional opinions as additional information, records and evidence become available.

Mr. Rhodes will further testify regarding any and all relevant matters addressed in his deposition, if taken in this case. Mr. Rhodes will further testify regarding any and all other matters raised by Plaintiff's experts that are within his area of expertise. Mr. Rhodes may supplement his opinions, as additional evidence becomes available. Mr. Rhodes may use diagrams and illustrations in support of his testimony, and he may use relevant documents from the case files, depositions, trial transcripts, or other discovery documents in support of his testimony. Mr. Rhodes may be asked to comment on any literature that is relevant to the issues in this case.

Respectfully submitted this 13th day of July 2018.

By: *s/ David C. Van Dyke*
David C. Van Dyke
Howard & Howard Attorneys PLLC
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Attorneys for Defendant Wright Medical Technology, Inc.

By: *s/ Scott A. Neckers*
Daniel R McCune, #14900
Scott A. Neckers, #
CHILDS MCCUNE LLC
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Attorneys for Defendant Wright Medical Technology, Inc.

CERTIFICATE OF SERVICE

I hereby certify on this 13th day of July 2018, a true and correct copy of the foregoing **DEFENDANT WRIGHT MEDICAL TECHNOLOGY, INC.'S F.R.C.P. 26(a)(2) EXPERT DISCLOSURE** was filed and served via electronic mail upon the following:

George E. McLaughlin Thomas R. Leemon Warshauer-McLaughlin Law Group, P.C. 1890 Gaylord Street Denver, CO 80206 gem@w-mlawgroup tleemon@w-mlawgroup.com	( ) U.S. Mail, first-class, postage pre-paid ( ) Hand Delivery ( ) Facsimile (X) Electronic Mail ( ) CM/ECF

Attorneys for Plaintiffs

s/ Melinda Perez

Exhibit A

Curriculum vita

Stephen Park Rhodes, MSE

Biologics CONSULTING | PHARMACEUTICALS, DEVICES & BIOLOGICS ADVISORS

CURRICULUM VITAE

Stephen Rhodes, MS

Senior Consultant

Biologics Consulting Group, Inc.
1555 King Street, Suite 300 • Alexandria, VA 22314
Phone: 703.739.5695 • Fax 703.548.7457
Email: srhodes@biologicsconsulting.com
BiologicsConsulting.com

EXPERIENCE

Medical Devices, Biologics Consulting Group, Inc, *Senior Consultant*
Alexandria, VA (March 2010 – Present)

- Provides regulatory support to clients on devices, biomaterials, combination products and tissues.
- Prepares FDA submissions, including 510(k)s, IDEs, Pre-Submissions, PMAs, 513g's, HDEs, Requests for Designations, Tissue Reference Group Petitions.
- Prepares regulatory strategy documents that include the optimal regulatory pathway, regulatory issues and considerations, appropriate indications and performance claims, and biocompatibility, bench, animal and human testing.
- Assists firms with executing a successful initial contact with FDA, serves as FDA contact person, interacts with FDA on behalf of clients, and assists firms preparing for FDA meetings and discussions.
- Advises companies in the design and conduct of preclinical studies and clinical trials for regulatory submissions, including GLP and GCP requirements.

Food and Drug Administration, Office of Device Evaluation, *(*1989 – 2010)

Director, Investigational Device Exemption (IDE) and Humanitarian Device Exemption (HDE) Programs (2007-2010)

- Responsible for developing and interpreting FDA policy and procedures on medical device clinical trials (IDEs) and orphan device approvals (HDEs).
- Responsible for the premarket Good Clinical Practice programs for devices
- Served as the CDRH representative on five working groups responsible for the Title VIII (ClinicalTrials.gov) provisions of FDAAA.
- Served as the CDRH Product Jurisdiction Officer, responsible for the CDRH recommendations on which FDA Center should take the lead on regulating combination products and improving the consistency in the review of these products.
- Served as the CDRH representative on the FDA Human Subject Protection Committee, Subcommittee on the Inclusion of Individuals with Impaired Decision-Making in Research, Emergency Research Consultative Board, Good Laboratory Practices Working Group, Tissue Reference Group.
- Led the Center for Devices and Radiological Health (CDRH) implementation of two titles of the Food and Drug Administration Amendments Act of 2007 (FDAAA): the Pediatric Medical Device Safety and Improvement Act of 2007 and the Clinical Trials Databases (ClinicalTrials.gov).

Acting Deputy Division Director, Division of General, Restorative and Neurological Devices (2005)

- Provided leadership on scientific, clinical and regulatory issues to the members of the Orthopedic Devices Branch and the Restorative Devices Branch.
- Final signatory on IDE Supplements, 510(k) applications, and PMA Supplements.
- Prepared staff for public advisory panel meetings and provided guidance to 510(k), IDE and PMA review teams.

Acting Deputy Division Director, Division of General, Restorative and Neurological Devices (2002)

- Provided leadership for the Plastic and Reconstructive Surgery Devices Branch and the General Surgery Devices Branch.
- Represented the agency at public meetings and conferences and discussions with industry on specific device applications.

Acting Deputy Division Director, Division of Cardiovascular and Respiratory Devices (2001)

- Provided leadership to 25 staff members in the Pacing, Defibrillator and Leads Branch, the Cardiac Electrophysiology Monitoring Devices Branch, and the Anesthesiology and Respiratory Devices Branch.
- Final signatory on IDE Supplements, 510(k) applications, and PMA Supplements for cardiovascular devices.
- Provided guidance to 510(k), IDE and PMA review teams.

Branch Chief, Plastic and Reconstructive Surgery Devices Branch (1996 - 2007)

- Managed the engineering, medical and clinical review of the data and subsequent approval of the following first-of-a-kind medical devices that have had a significant impact on public health:
    - the first approved saline-filled and silicone gel-filled breast implants
    - the first cyanoacrylate tissue adhesive
    - the first cyanoacrylate neuroembolization device
    - the first dural sealant
    - the first neurological stent for atherosclerosis
    - the first neurological stent for aneurysms
    - the first sealant for pulmonary surgery
    - the first sealant for cranial surgery
    - the first hyaluronic acid dermal filler
    - the first dermal filler for lipoatrophy in patients with HIV
    - the first non-viable human cellular product, for burn patients
    - the first viable human cellular product, for chronic ulcers
- Managed interdisciplinary staff consisting of 13 employees with diverse backgrounds, including chemistry, biology, veterinary medicine, cell biology, pathology, biomaterials, biomedical engineering, engineering mechanics, general surgery and occupational therapy
- Managed the regulation of a variety of important medical devices, including breast implants, liposuction devices, reconstructive implants, artificial skins, wound dressings, sutures, synthetic and tissue dura substitutes, neurological embolization devices, neurological stents, nerve repair devices, synthetic and tissue surgical meshes, lung sealants, stents and valves, tracheal prostheses, abdominal adhesion barrier products, cyanoacrylate tissue adhesives, and synthetic and tissue hemostatic agents.
- Regulated a unique number of products that involve collaboration with the Center for Drugs and/or the Center for Biologics and raise important policy issues for the agency, such as human dura, xenograft products, human cellular skin substitutes, and devices with antibiotics.

Team Leader, Orthopedic Devices Branch (1995)

- Oversaw the review of data for new orthopedic devices.

Engineering Reviewer, Orthopedic Devices Branch (1989 – 1996)

- For five years reviewed most of the new artificial knee devices in the agency.
- Served as the agency's expert on artificial knee devices and arthroscopes. Developed the engineering testing necessary to evaluate the safety and effectiveness of new artificial knees.
- Sole author of the guidance documents for artificial knees and arthroscopes detailing the engineering and

scientific information needed to evaluate the devices.
- Evaluated a variety of new orthopedic devices, including spinal implants, hip implants, shoulder implants, and ankle implants.
- Represented the agency in national and international organizations for the development of new test methods for orthopedic devices.
- Presented papers at scientific meetings on technical and regulatory issues to the orthopedic industry.

Non-FDA Experience

- 1987 – 1990
  - Reliability Engineer, Atlantic Research Corporation
  - Consultant on numerous NASA and DOD contracts

EDUCATION

M.S. *Device Biomedical Science and Technology Management,* Georgetown University/Virginia Tech, Washington, D.C. (2008)

M.S. *Biomedical Engineering,* The Catholic University of America, Washington, D.C. (1989)

B.S. *Engineering Science and Mechanics,* Virginia Tech, Blacksburg, Virginia (1986)

SELECT AWARDS

▪ BCG - Top Earner, New Employee	2011
▪ PHS - Outstanding Unit Citation (2 times total)	2007
▪ PHS - Unit Commendation (10 **times total)**	2006
▪ PHS - Outstanding Service Medal	2002
▪ PHS - Commendation Medal	2005
▪ PHS - Achievement Medal (2 times total)	2005
▪ FDA Group Recognition Award	2005
▪ FDA Engineer of the Year, National Society of Professional Engineers	2006
▪ FDA Outstanding Service Award (Group)	2006
▪ CDRH Scientific Achievement Award - Outstanding Intercenter Scientific Collaboration	2005
▪ PHS – Outstanding Service Medal	2002
▪ CDRH Excellence i**n Review Science Group Award**	1997
▪ CDRH Group **Productivity Incentive Award**	1996
▪ PHS – Engineering Literary Award – Regulatory Science	1995

FDA RELATED PRESENTATIONS AND PUBLICATIONS

- "Regulation of Medical Devices for Regenerative Medicine," 4th Annual Regenerative Medicine Conference, Berkeley, CA, May 2014.
- "Regulatory Perspectives on the Use of Toxicology Testing in Device Applications," 33rd Annual Meeting of the American College of Toxicology, Orlando, FL, November 2012.
- "Device Clinical Studies: Considerations for Evaluating Effectiveness," 6th Annual Device Research and Regulatory Conference, Society of Clinical Research Associates, Orlando, FL, May 2012.
- "Regulation of Combination Products," RAPS Online University, Course Contributor, 2012.
- "The Practice of Medicine and Government Regulations: The Rubicon," 2nd Annual Clinical Meeting of the Cell Society, Coronado, CA, February 2012.
- "Regulatory Aspects of the Pathway from Benchtop to Bedside for Devices," 2011 World Conference on Interventional Oncology," New York, NY, June 2011.
- "510(k) Update: Impact on Preclinical Testing," MD&M West 2011 Conference, Anaheim, CA, February 2011.
- Rhodes SP and Harvey ED, "HUDs and HDEs: Common Misconceptions and Current Challenges," in: Regulatory Focus, January 2011.
- "Clinical Trial Designs for Medical Devices to Meet Regulatory Requirements on Premarket Conformity Assessment," AHC Workshop on Medical Devices, Seoul, Korea, November 2010.
- "Point of Care Devices Versus Combination Products," RAPS 2010 Conference, San Jose, CA, October 2010.
- "Device Issues in Combination Products," RAPS 2010 Conference, San Jose, CA, October 2010.
- "Medical Devices, Combination Products – What Does the Future Hold?" Cellular Therapy: Biologic, Device or Biologic Device?, American Association of Blood Banks Annual Meeting, Baltimore, MD, September 2010.
- "Presubmission Meetings and Communication with FDA for 510(k)s, IDEs and PMAs" and "Best Practices and Useful Tips for 510(k)s, IDEs and PMAs," Medical Device Submission & Compliance Strategies for the US Market, RAPS, Brussels Belgium, November 2009
- "What is the Content and Format of Device Applications," "How Can Sponsor's Utilize Pre-Submission Consultation," and "What Clinical Data from Outside the US Does FDA Accept?" FDA's Total Product Lifecycle – Regulatory Pathways to Medical Device Marketing in the
- United States, Tel Aviv, Israel, September 2009
- "Adverse Event Reporting During Device Trials" and "Humanitarian Device Exemptions," Association of Clinical Research Professionals (ACRP) Annual Conference, Denver, CO, April 2009
- "The IDE Regulations," IDE Submission Workshop, Medical Technology Learning Institute, Las Vegas, NV, February 2009
- "Postapproval Studies and the Pediatric HDE Provisions of FDAAA;" "Panel Discussion: Current Initiatives with the FDA;" and "FDAs Investigational Device Exemption (IDE) Regulations – Balancing Science with the Needs of Patients." 2008 Annual Public Responsibility In Medicine & Research (PRIM&R) Conference, Lake Buena Vista, FL, Nov 2008
- "The Device Regulations and Good Clinical Practices (GCPs)," Annual Human Subject Protections Conference, Covington, KY, Sept 2008

- "Pre-IDE Process: Optimizing Your Results," RAPS Annual Conference, Boston, MA, Sept 2008
- "Combination Products Overview," 2008 Parental Drug Association (PDA)/FDA Joint Regulatory Conference, Washington, DC, Sept 2008
- "Humanitarian Device Exemptions for Pediatric Devices," Pediatric Medical Devices Stakeholders Workshop, NIH, Bethesda, MD, July 2008
- "Regulatory and Design Considerations for Clinical Research of Medical Devices," Association of Clinical Research Professionals (ACRP) Global Conference on Human Subjects, Boston, MA, April 2008
- "The Regulatory Aspects of Hyperthermia Studies," ESHO Educational School on Clinical Hyperthermia, Munich, Germany, April 2008
- "FDA Amendments Act of 2007: HDE Provisions of Title III – Pediatric Medical Device Safety and Improvement Act of 2007," Pediatric Medical Device Innovation, Regulation and Legislation Seminar, Medical Technology Learning Institute, Falls Church, VA, April 2008
- "The Legal Basis for an IDE Submission," IDE Submission Workshop, Medical Technology Learning Institute, Las Vegas, NV, February 2008
- "IDEs and HDEs for IRBs and Clinical Investigators," IRB Educational Conference, University of Medicine and Dentistry of New Jersey, Cancer Institute of New Jersey, New Brunswick, NJ, January 2008
- "The FDA's Investigational New Drug and Investigation Device Exemption Regulations" and "Medical Device Postapproval Studies," 2007 Annual Human Research Protection Program Conference, Boston, MA, December 2007
- "CDRH Regulation of Tissue Engineered Medical Products," 30th Annual Meeting of the Society of Biomaterials, Memphis, TN, April, 2005.
- "CDRH Perspective on the Regulation of Cyanoacrylate Tissue Adhesives," 30th Annual Meeting of the Society of Biomaterials, Memphis, TN, April, 2005.
- "FDA Perspective on the Regulation of Medical Device Tissue Adhesives," in: *Tissue Adhesives In Clinical Medicine*, BC Decker, Inc., 2005.
- "Regulatory Issues for Medical Devices," in: *Textbook of Cerebrovascular Intervention*, Saunders, 2005.
- "CDRH Perspective on the Regulation of Biomaterials in Plastic and Reconstructive Surgery Devices," 7th World Congress of Biomaterials, Sydney, Australia, May 2004.
- "CDRH Perspective on the Regulation of Novel Wound Dressings," DARPA Wound Healing Workshop, Baltimore, MD, September 2003.
- "Clinical Studies and Least Burdensome Issues," MASSMedic Annual Meeting, Boston, MA, March 2003.
- "Regulation of Tissue-Engineered Products by FDA," Georgia Institute of Technology Short Course on Tissue Engineering, April 1997.
- "The Regulation of New Total Knee Prostheses," *Journal of Long-Term Effects of Medical Implants,* 4(1):1994.
- "The Evaluation of the Safety and Effectiveness of Total Knee Prostheses," Thirteenth Southern Biomedical Engineering Conference, April 1994.
- "The Regulation of Revision Hip Prostheses," Orthopaedic Research Symposium on "Current Concepts in Total Hip Revision Surgery," November 1993.

EXHIBIT B

Direct Dial: 312.456.3421

Tiffany L. Carpenter
Attorney and Counselor

E-mail: tlc@h2law.com

December 10, 2018

Via E-Mail
Thomas R. Leemon
George E. McLaughlin
Warshauer-McLaughlin Law Group, P.C.
1890 Gaylord Street
Denver, CO 80206
tleemon@w-mlawgroup.com
gem@w-mlawgroup.com

Re: Applekamp v. Wright Medical Technology, Inc.;
Case No. 1:17-cv-01601

Dear Counsel:

In an attempt to resolve our dispute regarding the marking of Stephen Rhodes's deposition as confidential, we have reviewed the transcript again and, in the interest of compromise, we are limiting those sections of the transcript designated as confidential. We hope you will accept our compromise position so that we need not involve the Court in the resolution of this issue.

Pursuant to Sections 2.02 and 3.03 of the Protective Order entered in this case, Wright Medical Technology, Inc. designates the following exhibits and pages and lines of Stephen Rhodes, MSE's October 8, 2018, deposition transcript as CONFIDENTIAL: Exhibits: 3-5, 8-14 and pages and lines: 55: 10-56: 13; 59: 14-63: 8; 63: 9-23; 72: 17-73: 20; 74: 3-75: 14; 77: 10-79: 7; 80: 8-22; 91: 23-102: 6; 104: 1-110: 25; 111: 1-113: 21; 113: 22-120: 1; 120:2-121: 11; 122: 2-16; 122:17-129: 25; 130: 25-131: 18; 136: 2-137: 22.

Please let us know if you have any questions or concerns.

Respectfully,

HOWARD & HOWARD ATTORNEYS PLLC

Tiffany L. Carpenter

cc: Daniel R. McCune and Scott A. Neckers - Childs McCune, LLC
(*dmccune@childsmccune.com*; *sneckers@childsmccune.com*)

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

- - - - - - - - - - - - - - -x

SCOTT APPLEKAMP and :
GAIL APPLEKAMP, :
Plaintiffs, : Case No.
v. : 1:17-cv-01601-CBS
WRIGHT MEDICAL :
TECHNOLOGY, INC., a :
Delaware Corporation, :
Defendant. :

- - - - - - - - - - - - - - -x

CONFIDENTIAL

Deposition of STEPHEN PARK RHODES, MSE

Washington, DC

Monday, October 8, 2018

10:50 a.m.

Job No.: 27677cc
Pages: 1 - 150
Reported By: Janet A. Hamilton, RDR

Deposition of STEPHEN PARK RHODES, MSE, held at the offices of:

Planet Depos - DC
1100 Connecticut Avenue, NW
Suite 950
Washington, DC 20036
888.433.3767

Pursuant to notice, before Janet A. Hamilton, Registered Diplomate Reporter and Notary Public in and for the District of Columbia.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFFS:

THOMAS R. LEEMON, ESQUIRE
WARSHAUER-McLAUGHLIN LAW GROUP, P.C.
1890 Gaylord Street
Denver, Colorado 80206-1211
720.420.9800

ON BEHALF OF THE DEFENDANT:

DAVID C. VAN DYKE, ESQUIRE
HOWARD & HOWARD ATTORNEYS, PLLC
200 South Michigan Avenue
Suite 1100
Chicago, Illinois 60604
312.372.4000

MR. VAN DYKE: When you get to a good break point, I need a break.

MR. LEEMON: Okay. We can take a break.

(A recess was taken.)

BY MR. LEEMON:

Q Back on the record. Mr. Rhodes, do you understand that you're still under oath?

A Yes.

Q In your experience at the FDA how many 510(k) submissions were you involved with?

A Thousands.

Q Were you the lead reviewer on all of those?

A No.

Q Approximately how many of the 510(k) submissions when you were employed by the FDA were you the lead reviewer?

A Three to 500.

Q You mean 300 to 500?

A 300 to 500.

Q I -- I may be incorrect, but I thought you said 3 to 500.

A Oh.

Q I thought I knew what you meant. I was just trying to make the record clear.

withdraw 510(k)s.

Q Do they ever recommend that a component of a 510(k) be, of the 510(k) submission be withdrawn?

A No.

Q All right. How many PMAs -- actually let me ask a better question. What does PMA stand for?

A Premarket approval.

Q And is that a different regulatory path for a medical device to obtain market access?

A Yes.

Q What are the differences between the PMA process and the 510(k) process?

A Well, they're -- the data requirements are different. The review processes are different. It's all laid out in the, in the regulations and in guidance.

Q Do PMAs usually include clinical data?

A Yes.

Q And how is that clinical data obtained?

A A clinical study.

Q What's an IDE?

A Investigational device exemption. It's a clinical study in the US.

Q Do most manufacturers use an IDE to obtain clinical data to submit in their PMA?
A If the study's in the US, yes.
Q Does a 510(k) usually include clinical data?
A Usually, no.
Q Approximately what percentage of 510(k) submissions include clinical data?
A It's about 10 percent.
Q I reviewed a guidance document that referenced eight percent. Would you have any reason to disagree with that?
MR. VAN DYKE: Objection, form.
A No.
Q What's the user fee associated with a PMA submission?
A Well, it changes every year.
Q Approximate amount is okay.
A 240,000 I think.
Q Are you referencing back in the 2000 range or --
A No.
Q -- present?
A Present.
Q How much --

respect to a 510(k)?

A I think that somebody has published average numbers. I -- I don't know. I don't know what the averages are.

Q So if the FDA publishes average decision time frames with respect to 510(k) and PMA submissions, you would generally defer to whatever the FDA publishes; right?

A Yes.

Q Are the terms clearance and approval terms of art with respect to FDA regulatory issues?

A You're asking me what is a term of art? Is that what your question is?

Q Well, does clearance with respect to a 510(k) submission have a specific definition or a specific meaning?

A It's how Class 2 devices are allowed on the market via clearance.

Q If the FDA says to a manufacturer that a device is cleared, does that mean that the FDA has approved the safety and efficacy of a device?

A No.

Q Is there a specific regulation that confirms, that confirms FDA clearance does not mean FDA approval?

A There's a regulation that companies are not allowed to advertise that their 510(k) products are approved, if that's what you're referring to.

Q What is that regulation? Do you have a specific cite?

A I don't know the number offhand.

Q So what is your understanding of the differences between the term clearance and the term approval with respect to FDA regulatory issues?

A Clearance is the term used for 510(k)s, and approval is the term used for PMAs.

Q And what's your understanding of the differences between those terms, what they mean, what clearance means as opposed to what approval means?

A So clearance means that a company has submitted a 510(k). FDA has evaluated that 510(k) and found that that device is substantially equivalent to a predicate or predicate devices.

Approval means that a company submitted a PMA and the FDA has evaluated that safety and effectiveness information and determined that there was a reasonable assurance of safety and

effectiveness of that PMA product.

Q Are the evidentiary standards between a 510(k) submission and PMA submission different?

A Evidentiary standards? I think both require that, that the data be consistent, that it be reproducible, that it be, you know, valid. So all, all the data that FDA reviews in 510(k)s and PMAs they rely on valid scientific evidence. That's what I would call the evidentiary standard.

Q So let's talk about the Profemur R Revision Hip System, the 510(k) submission K003016. What valid scientific evidence did Wright Medical provide to the FDA with respect to that submission?

A Okay. So they provided I'd say engineering drawings. They provided a device description. They provided information about what the materials were made of, how they interacted, any surface treatments that were on those devices. They did fatigue testing of the stem and neck and head components. They looked for fretting and corrosion. I -- and I -- I would also put the labeling that they provided as scientific evidence. They also had information about the sterilization and consensus standards that they