

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

September 28, 2010

Via Electronic Transmission

The Honorable Eric K. Shinseki
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary Shinseki:

As a senior member of the United States Senate and the Ranking Member of the Committee on Finance (Committee), I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the United States Department of Veterans Affairs (VA/Agency). In this capacity, I must ensure that VA, as the primary federal agency responsible for the health care of veterans, properly fulfills its mission to “provide veterans with world-class benefits and services” and makes responsible use of the public funding provided to accomplish this task.

For the last several years I have worked to achieve public disclosure of financial relationships between physicians and the drug, device, and biologic industries. Beginning in the summer 2008, I began releasing information to demonstrate that universities were not managing their professors’ financial conflicts of interest and that change was needed at the NIH. Specifically, I found:

- The Chair of the Psychiatry Department at Emory University failed to report hundreds of thousands of dollars in payments from a pharmaceutical company while researching that same company’s drugs with an NIH grant. The Health and Human Services Office of Inspector General (HHS OIG) is now investigating the matter.
- The Chair of the Psychiatry Department at Stanford University received an NIH grant to study a drug, while partially owning a company that was seeking FDA approval of said drug. He was later removed from the grant.
- Three psychiatrists at Harvard University failed to report almost a million dollars each in outside income while heading up several NIH grants. Harvard plans to release a report on the matter.

Today, I am writing to you regarding information that I received related to Dr. Stephen L. Ondra, who was appointed by President Obama as the Senior Policy Advisor for Health Affairs for the VA on May 10, 2009. Prior to joining the VA, Dr. Ondra served on the Veterans Affairs group in the Obama-Biden Presidential Transition Team, as well as, on the Obama-Biden Campaign Health Policy and Veteran's Policy committees. Dr. Ondra also chaired the Scientific Advisory Board for the Defense Spinal Cord and Column Injury Project for the Department of Defense and served on the Centers for Medicare and Medicaid Services' Medical Coverage Advisory Committee. (See Attachment A)

In addition, according to the information obtained by my Committee staff, Medtronic paid Dr. Ondra for consulting services and speaking engagements, as well as, millions in royalty payments, while he was Director of Spine Surgery at Northwestern University. In total, Medtronic paid Dr. Ondra almost \$4 million over the two year period immediately prior to his becoming part of the Obama Administration. Dr. Ondra was also the principal investigator or active participant on six recent studies focusing on the spine. Each of these studies was funded by Medtronic Sofamor Danek.¹

As President-elect, President Obama released what was known as the Obama-Biden Plan, which stated that the new Administration would "Free the Executive Branch from Special Interest Influence." Specifically, "No political appointees in the Obama-Biden administration will be permitted to work on regulations or contracts directly and substantially related to their prior employer for two years."²

While Dr. Ondra was not an employee of Medtronic, he acted as an agent of the company when promoting and speaking about medical devices on its behalf. Dr. Ondra's relationship with Medtronic not only benefited him financially while he was practicing medicine and representing Northwestern University, but it also appears to have been a factor in getting him the position as Senior Policy Advisor for Health Affairs at the VA.

I suggest that is the case based upon an email sent by the Chairman of the Board, President and Chief Executive Officer of Medtronic, William Hawkins, III to Medtronic Senior Vice President and head of the spinal and biologics unit, Steve La Neve, on January 16, 2009. In that email, Mr. Hawkins said:

I spoke this afternoon with Dr. Casscells, current Assistant Secretary of Defense for Health Affairs, regarding the process by which we might recommend a candidate to replace him in the new administration. I have known Dr. Casscells for many years and was comfortable in approaching him on this topic.

¹ Biographical Sketch of Stephen L. Ondra www.feinberg.northwestern.edu/.../Ondra%20Biosketch.doc

² The Obama-Biden Plan, available at http://change.gov/agenda/ethics_agenda.

He welcomed my call and indicated that recommendations from CEOs were very important. Dr. Casscells indicated that the decision to replace him would be made by Secretary of Defense, Robert Gates, and the President of the United States. Dr. Casscells suggested that I write a letter to Secretary Gates recommending Steve Ondra. Dr. Casscells knows of Dr. Ondra. In fact, he is planning to have coffee with him next week.³ (*See Attachment B*)

Mr. Hawkins then instructed Mr. La Neve to draft the letter to Secretary Gates.

Secretary Shinseki, the public has the right to know whether or not Dr. Ondra's policy advice and decisions at the VA are vulnerable to potential conflicts of financial interest. Again, I recognize that Dr. Ondra was not an employee of Medtronic per se, but his relationship with Medtronic is unambiguous and substantial. It is also apparent that as a result of his relationship with Medtronic, Dr. Ondra was able to penetrate the political establishment at its highest level to obtain a senior position at the VA. Interestingly, a document provided to me in response to document production in another matter went so far as to identify possible Administration positions for which he might qualify. (*See Attachment C*) Thus, in the interest of transparency and accountability, I would appreciate the VA's response to the following questions. When preparing responses, please restate the question and follow with the responsive information.

- 1) Prior to his appointment as VA's Senior Policy Advisor for Health Affairs, what was disclosed to the Agency regarding Dr. Ondra's financial interests over the last five years? Please provide documentation of these disclosures.
- 2) Please provide all emails between Dr. Ondra and Medtronic from March 2009 to the present. This request includes all emails by and between Dr. Ondra and Medtronic from March 2009 to the present for both Dr. Ondra's VA and private accounts, including his Comcast account.
- 3) In his position as Senior Policy Advisor for Health Affairs, does Dr. Ondra have any contact with Medtronic? If so, what is his level of interaction with the company and how is that interaction managed, if at all?
- 4) Is and/or has Dr. Ondra been recused from issues related to Medtronic and spine treatments? If so, please provide documentation.
- 5) Please describe in detail the VA's policies and protocols related to conflicts of interest and the management of conflicts for its highest level employees, like Dr. Ondra.
- 6) Please provide Dr. Ondra's conflict of interest/financial disclosure forms from 2009 to the present.

³ Email message from William Hawkins to Steve La Neve on January 16, 2009.

Thank you for your attention and assistance on this matter. I would appreciate your response to my questions by no later than October 13, 2010. Should you have any questions regarding this letter, please do not hesitate to contact Angela Choy at (202) 224-4515. Any formal correspondence should be sent electronically in PDF searchable format to Brian_Downey@finance-rep.senate.gov.

Sincerely,



Charles E. Grassley
Ranking Member

Attachments

Attachment A

**UNITED STATES
DEPARTMENT OF VETERANS AFFAIRS****Stephen L. Ondra****Senior Policy Advisor for Health Affairs**[Print Version](#)

Dr. Stephen Ondra, M.D., was appointed as Senior Policy Advisor for Health Affairs in the Department of Veterans Affairs (VA) by President Obama on May 10, 2009. Prior to that, he served on the Veterans Affairs group in the Obama-Biden Presidential Transition Team, as well as on the Obama-Biden Campaign Health Policy and Veteran's Policy committees.

Dr. Ondra first entered government service as a Cadet at the U.S. Military Academy. After receiving injuries in a training accident, Dr. Ondra completed pre-medical studies at Illinois Wesleyan University. By his graduation in 1984, Dr. Ondra had recovered sufficiently from his injuries to allow him to re-enter Army service while earning his doctorate at Rush Medical College in Chicago, Ill. He completed his residency training at Walter Reed Army Medical Center in Washington, D.C., where he received specialized instruction in spine surgery and reconstruction in both the neurosurgery and orthopedic specialties.

Dr. Ondra was deployed to Saudi Arabia from 1990 to 1991 in support of Operations Desert Shield and Desert Storm. His service was recognized with a Bronze Star and Army Commendation Medal. Following his deployment, he was assigned to Walter Reed and became the Director of Spine and Skull-base Surgery.

After leaving military service in 1994, Dr. Ondra joined the Clinical Faculty at the University of Michigan. In 1996, he moved to Illinois' Northwestern University, where he served as the Residency Program Director Vice Chair, Director of Spine Surgery, Director of the Spinal Deformity Fellowship, Director of Spine Research, and Medical Director of the Neuro-Spine Intensive Care Units. He also chaired the Medical Device and Technology Committee at Northwestern Memorial Hospital. In 2006, he was promoted to Professor of Neurological Surgery at Northwestern.

In parallel to his medical work in both the military and civilian worlds, Dr. Ondra has worked with several Government agencies. He chaired the Scientific Advisory Board for the Defense Spinal Cord and Column Injury Project for the Department of Defense, and served on the Medical Coverage Advisory Committee with the Centers for Medicare and Medicaid Services at the Department of Health and Human Services. His medical expertise has allowed him to advise and discuss health policy matters with members of Congress, Cabinet Members and foreign government leaders.

Dr. Ondra and his wife Cindy have three daughters.

U.S. Department of Veterans Affairs - 810 Vermont Avenue, NW - Washington, DC 20420

Reviewed/Updated Date: July 14, 2010

Resume for Stephen L. Ondra, MD
December 7, 2008

Stephen L. Ondra is a native of Illinois and graduated from Bradley-Bourbonnais High School. He attended the United States Military Academy at West Point. After being injured in training, pre-medical studies were completed at Illinois Wesleyan University. He continued military service while attending Rush Medical College in Chicago. After graduation in 1984, he completed internship and residency training in neurological surgery at Walter Reed Army Medical Center in Washington, DC. During his residency, he received specialized instruction in Spine Surgery and Reconstruction in both Neurosurgery and Orthopedic Surgery.

After training, Dr. Ondra served at William Beaumont Army Medical Center in El Paso, Texas. In 1990-91, he was deployed to Saudi Arabia where he served with distinction during Operation Desert Shield and Desert Storm. He was awarded a Bronze Star and Army Commendation medals for his service. After returning from the war, he was transferred to Walter Reed where he served as Director of Spine and Skull Base Surgery.

Leaving the service in 1994, Dr. Ondra pursued private practice in Ann Arbor, Michigan and served on the Clinical Faculty at the University of Michigan. In 1996, he joined the faculty of Northwestern University in Chicago, Illinois. At Northwestern, Dr. Ondra serves as the Residency Program Director, Vice Chair, Director of Spine Surgery, Director of the Spinal Deformity Fellowship, Director of Spine Research and Medical Director of the Neuro-Spine Intensive Care Units. He Chairs the Medical Device and Technology Committee at Northwestern Memorial Hospital. This committee reviews and approves purchases of all medical devices at that institution. He was promoted to Professor of Neurological Surgery at Northwestern in 2006.

Dr. Ondra has authored numerous scientific papers and book chapters. He is a highly sought after speaker and is considered a world expert in many areas of spine surgery. He has developed new surgical procedures, equipment and has received grant awards in excess of \$2.5 million.

Outside of clinical and academic medicine, Dr. Ondra has worked with the Department of Defense as the past Chairman of the Scientific Advisory Board for the Defense Spinal Cord and Column Injury Project. He is the current Chair of the Scientific Advisory Board of the Defense Blast Spinal Cord Injury Project. Dr. Ondra also continues to be an independent consultant for the Department of Defense Health Services Command. Dr. Ondra is a Board Member of the Shelton Foundation for Military Neurotrauma Research. In addition to the Department of Defense, Dr. Ondra serves on the Medical Coverage Advisory Committee with the Centers for Medicare and Medicaid Services at the Department of Health and Human Services. He was reappointed to a second four year term in this capacity in 2006. His expertise in healthcare matters has allowed him to advise and discuss health policy matters with members of the United States Congress, Cabinet Members and foreign government leaders. Dr. Ondra has been interviewed in the media for his expertise in a variety of subjects ranging from spinal disease, combat

medical care, industry-physician relations, technology development and the medical-legal affairs.

Dr. Ondra has provided input to the Obama Senate office on issues involving military and veteran's health care. During the Presidential campaign, Dr. Ondra served on the Health Policy and Veteran's Policy committees for the Obama-Biden campaign. He is a member of Doctors for Obama and served as a regional director. As a member of Veterans for Obama, he was a state co-Chair. Doctor Ondra was a Senior Health Policy Advisor for the Dan Seals Congressional campaign. He is also a member of the Democratic National Committee and the Democratic Congressional Campaign Leaders Circle.

Dr. Ondra lives in Wilmette with his wife Cindy and their three daughters.

Steve Ondra
[REDACTED]
[REDACTED]

Mobile Phone: [REDACTED]
Home Phone : [REDACTED]
Email : [REDACTED]

Stephen L. Ondra, MD
Professor and Program Director
Department of Neurological Surgery
Northwestern University
676 N. St. Clair, Suite 2210
Chicago, IL 60611

Phone: [REDACTED]
Fax: [REDACTED]
E-mail: [REDACTED]

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Ondra, Stephen Louis	POSITION TITLE Professor of Neurological Surgery		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
United States Military Academy (West Point, NY)		1975-1978	
Illinois Wesleyan University (Bloomington, IL)	B.A.	1978-1980	Biology
Rush Medical College (Chicago, IL)	M.D.	1980-1984	Medicine/Neurosurgery

A. Positions and Honors.**Positions and Employment**

1984-1985	Surgical Internship, Walter Reed Army Medical Center
1985-1990	Neurosurgical Residency, Walter Reed Army Medical Center
1990-1991	Staff Neurosurgeon, William Beaumont Army Medical Center
1990-1991	Chief of Neurosurgery, 8 th Evacuation Hospital, Saudi Arabia
1991-1994	Staff Neurosurgeon and Assistant Professor of Neurosurgery, Walter Reed Army Medical Center
1992-1994	Assistant Professor of Neurological Surgery, Uniformed Services University of Health Sciences
1992-1994	Director of Skull Base Surgery, Walter Reed Army Medical Center
1993-1994	Director of Complex Spine Surgery, Walter Reed Army Medical Center
1995-	Adjunct Professor of Neurological Surgery, Uniformed Services University of Health Sciences
1995-1998	Clinical Faculty, University of Michigan Hospital Hospitals
1996-2000	Assistant Professor of Neurological Surgery, Northwestern University Medical School
1998-	Vice-Chairman, Department of Neurological Surgery, Northwestern University Medical School
1998-	Residency Program Director, Department of Neurological Surgery, Northwestern University Medical School
1998-	Director, Fellowship in Spinal Reconstructive Surgery, Department of Neurological Surgery, Northwestern University Medical School
1998-	Executive Director, HealthSouth Back and Neck Institute, Northwestern Memorial Hospital
1999-	Medical Director, NeuroSpine Intensive Care Unit, Northwestern Memorial Hospital
2000-	Associate Professor of Neurological Surgery, Northwestern University Medical School
2001 -	Chairman, Scientific Advisory Board, Defense Spinal Cord and Column Injury, Department of Defense
2004 -	Medical Care Advisory Committee, Department of Health and Human Services

Other Experience and Professional Memberships

1994 -	Member, American Association of Neurological Surgeons
1997 -	Member, American College of Surgeons
1997 -	Board Member, American Association of Spine Physicians
1998 -	Member, Congress of Neurological Surgeons
2001-2002	Medical Ethics Committee, Northwestern Memorial Hospital
2001-2003	President, Illinois State Neurosurgical Society
2001 -	Executive Committee, AANS/CNS Joint Section on Spine/Peripheral Nerves
2001 -	Education Committee, Congress of Neurological Surgeons
2001-	Member, Society of University of Neurosurgeons
2003-	Quadrant Chair, Council of State Neurosurgical Societies
2004 -	Chair, Institute for Health Policy Research; Chicago, IL
2004-	Member, North American Spine Society
2004-	Member, Scoliosis Research Society
2005-	Member, Society of Neurological Surgeons

Honors

	Alpha Omega Alpha Honor Medical Society
	Phi Kappa Phi
2001	Visiting Professor, University of Texas, Southwestern
2002	Visiting Professor, University of Southern Florida
2002	Visiting Professor, University of Michigan
2003	Bennett-Tarkington Professor, Northwestern University Medical School

B. Selected peer-reviewed publications or manuscripts in press (in chronological order).

1. Ondra SL, George ED, Troupp H, Schwab K: The Natural History of Arteriovenous Malformation of the Brain: a 24 Year Follow-up. *Journal of Neurosurgery* 73: 387-91, September 1990.
2. Maurer PK, Ellenbogen RG, Ecklung JM, Simonds GR, Van Dam B, Ondra SL: Cervical Spondylotic Myelopathy Treated by Decompression and Luque Rectangle Fusion. *Neurosurgery* 28: 680-84, May 1991.
3. Donovan MG, Ondra SL, Illig JJ, Dickerson NC: Combined transmandibular-zygomatic approach and infratemporal craniotomy for intracranial skull base tumors. *Journal of Oral & Maxillofacial Surgery*. 51(7): 754-8, July 1993.
4. Meter JJ, Polly DW, Miller DW, Popovic NA, Ondra SL: A Method for Radiographic Evaluation of Pedicle Screw Violation of the Vertebral Endplate. *Spine* 21(13); 1587-1592, July 1996.
5. Ondra SL, Smith M: Endoscopic Lumbar Discectomy and Techniques. *Neurosurgery*; 1997
6. Ondra SL, Smith M.: Lumbar Foramenoscopic Microdiscectomy. *Techniques in Neurosurgery*, Vol 3:4, 1997
7. Few J, Marcus J, Lee MJ, Ondra SL, Dumanian G: Treatment of Hostile Midline Back Wounds: An Extreme Approach. *Plastic and Reconstructive Surgery*; June 2000
8. Coleman W, Benzel E, Ondra SL et al: A Critical Appraisal of the Reporting of the National Acute Spinal Cord Injury Studies (II and III) of Methylprednisolone in Acute Spinal Cord Injury. *Journal of Spinal Disorders*; Vol 13:3, pp 185-199, June 2000.
9. Salehi SA, Ondra SL: Use of internal fiducial markers in frameless stereotactic navigational systems during spinal surgery. *Neurosurgery*; 47(6), pp. 1460-2, December 2000.
10. Salehi SA, McCafferty RR, Karahalios D, Ondra SL. Neural Function Preservation and early Mobilization after resection of Metastatic Sacral tumors with Lumbar-Pelvic Junction Reconstruction. *Journal of Neurosurgery*. 97(1 Suppl): 88-93, July 2002.
11. Tawk R, Ondra SL, et al: Hypersegmentation, Klippel-Feil Syndrome, and Hemivertebra in a Scoliotic Patient. *Journal of the American College of Surgeons*; 195 (4): 570-1, October 2002.
12. Liu JC, Ondra SL, Angelos P, Ganju A, Landers ML. Is laparoscopic anterior lumbar interbody fusion a useful minimally invasive procedure? *Neurosurgery*; 51(5 Suppl):155-8, November 2002.
13. Rosner MK, Polly DW, Kuklo TR, Ondra SL. Thoracic Pedicle Screw Fixation for Spinal Deformity. *Neurosurgical Focus*; 14(1), January 2003.
14. Dumanian GA, Ondra SL, Liu J, Schafer MF, Chao JD. Muscle Flap Salvage of Spine Wounds with Soft Tissue Defects or Infection. *Spine*; 28 (11): 1203-1211, June 2003.
15. Mindea SA, Salehi SA, Ganju A, Rosner, MK, O'Shaughnessy BA, Jorge A, Ondra SL. Lumbosacropelvic junction reconstruction resulting in early ambulation for patients with lumbosacral neoplasms or osteomyelitis. *Neurosurgical Focus*; 15 (2): August 2003.
16. Deutsch H, Mummaneni PV, Haid RW, Rodts GE, Ondra SL. Benign Sacral Tumors. *Neurosurgical Focus*; 15(2): August 2003.
17. Reid RR, Dutra J, Conley DB, Ondra SL, Dumanian GA. Improved repair of cervical esophageal fistula complicating anterior spinal fusion: free omental flap compared with pectoralis major flap. Report of four cases. *Journal of Neurosurgery*. 100 (1 Suppl): 66-70, January 2004.
18. Salehi SA, Tawk R, Ganju A, LaMarca F, Liu JC, Ondra SL. Transforaminal Lumbar Interbody Fusion (TLIF): Surgical Technique and Results in Twenty-Four Patients. *Neurosurgery*; 54 (2): February 2004.
19. Rosner MK, Kuklo TR, Tawk R, Moquin R, Ondra SL. Prophylactic placement of an inferior vena cava filter in high-risk patients undergoing spinal reconstruction. *Neurosurgical Focus*; 17 (4): October 2004.
20. Morasch M, Ondra SL, Rodriguez H, Labropoulos N, Tawk R. The Prophylactic Use of Inferior Vena Cava Filters in Patients Undergoing High Risk Spinal Surgery. *Annals of Vascular Surgery: Selected Techniques*; 19(3): 442-447, May 2005.
21. Lee MJ, Ondra SL, Mindea SA, Fine NA, Dumanian GA. Indications and Rationale for Use of Vascularized Fibula Bone Flaps in Cervical Spine Arthrodeses. *Plastic and Reconstructive Surgery* 116(1): 1-7, July 2005.
22. Marzouk S, Ondra SL. Safety and efficacy of C2 pedicle screws placed with anatomic and lateral C-arm guidance. *Spine Journal (accepted, in press)*
23. O'Shaughnessy BA, Ondra SL, Ganju A, Said HK, Few JW, Liu JC. Anterior thoracic spine reconstruction using a titanium mesh cage and pedicled rib flap. *Spine*, 2005.(accepted, in press)

C. Research Support.

Adult Deformity Outcomes Analysis (ADO)

Conducted at: Northwestern University, Beth Israel Medical Center (NY), Brooklyn Spine Center (NY), Buffalo General Hospital (NY), Center des Massues Service (France), Emory Spine Center, IL Bone & Joint Inst., Maimonides Medical Center (NY) Meiji Hospital (Japan), Orthopaedic and Scoliosis LLC (IL), Panorama Orthopaedics (CO), Seoul Spine Institute (South Korea), Service de Chirurgie Ortho (France), Spine Institute (CA), Spine Institute (KY), UCSF (CA) University of Miami (FL), Washington University (MO), Woodridge Orthopaedic and Spine (CO)

Funding: Medtronic Sofamor Danek

Date: May 2004-Ongoing

While adolescent idiopathic scoliosis has been studied quite extensively, the natural history of spinal deformity in the adult is less well documented. The impression of most surgeons is that adult deformity progresses with aging, resulting in pain and disability. However, this has not been clearly documented in the literature. The overall purpose of this research is to evaluate the natural history of adults with significant spinal deformity by establishing a prospective adult spinal deformity database that will permit future studies to be done retrospectively with prospective data. Towards that goal, this study intends to examine both the incidence of symptoms and the effectiveness of non-operative and operative treatment interventions by assessing complications and fusion rates, radiographic and clinical outcomes as well as quality of life data to prove or disprove that a significant percentage of the older patients with degenerative changes are helped with surgery. All study data will be gathered from patient charts/medical records for after the subject has signed an informed consent document. This is a multi-center study that involves prospective collection of data from subjects' medical records/ charts and analysis of that data to better understand the natural history of spinal deformity in the adult.

Dr. Ondra is the Principal Investigator for this study.

PhDx Surgical Outcomes Assessment of Cervical Surgical, Lumbar Surgical, and Conservative Care

Conducted at: Northwestern University

Funding: Medtronic Sofamor Danek

Date: February 2004-Ongoing

In the Department of Neurological Surgery at Northwestern Memorial Hospital, a large number of patients with spinal disorders are evaluated and treated. Increasingly, in the health care business, both physicians and hospital will have to display cost-effectiveness and successful outcomes in order to maximize payment from third-party payors. This study represents an attempt to track surgical outcomes in the means of qualitative outcomes measurement tools, such as the SF-36 and Oswestry Pain Disability form.

Dr. Ondra (PI) is involved with recruitment and identification of proper candidates for this study. He is also involved with radiographic measurements and completion of clinic reporting forms.

Spine Research Collaboration: Gait Analysis and Spinal Deformity

Conducted at: Northwestern University, Rehabilitation Institute of Chicago

Funding: Medtronic Sofamor Danek

Date: 1/1/03 – 12/31/07

This project assesses the effect of spinal deformity and spinal fusion on gait. The ultimate goal will be to combine the finite element analysis of the spine with the gait laboratory data to attempt to accomplish a complete computer model of spine, pelvis, trunk, and extremity locomotion, taking into account the finite element analysis of each component. This will be done in conjunction with the gait lab at the Rehabilitation Institute of Chicago and the NU Department of Biomechanical Engineering.

Dr. Ondra is the Principal Investigator for this study.

Spine Research Collaboration: Cervical-Sagittal Plane Balance

Conducted at: Northwestern University, Rehabilitation Institute of Chicago

Funding: Medtronic Sofamor Danek

Date: 1/1/03 – 12/31/07

Focusing on cervical biomechanics, this study integrates with the cervical finite element model. The initial phase, which has been completed, was to obtain normative data. The second phase will be to obtain pre and post-operative pathological subjects for analysis and comparison to normals. We will then analyze clinical outcome and degree of correction normals.

Dr. Ondra is the Principal Investigator for this study.

Principal Investigator/Program Director (Last, First, Middle):

Spine Research Collaboration: Finite Element Analysis

Conducted at: Northwestern University, Rehabilitation Institute of Chicago
Funding: Medtronic Sofamor Danek
Date: 1/1/03 – 12/31/07

The goal of this study is to assemble a finite element model of the human spine. The purpose of this model is to provide a computer-based platform for the design and testing of implants, so as to better understand secondary disease processes such as adjacent level degeneration. This tool may also provide a platform for a preoperative planning tool, which could be used to optimize surgical outcomes. Initial focus will be on the cervical spine, including the occipitocervical junction. A burst fracture model and an oncology model will both be developed within a finite element framework. This model will be validated mechanically.

Dr. Ondra is the Principal Investigator for this study.

Morbidity of Anterior Exposure for Spinal Deformity (Scoliosis Research Society Study)

Conducted at: Northwestern University, Brooklyn Spine Center (NY), Emory Spine Center, Orthopaedic and Scoliosis LLC (IL), Spine Institute (KY) UCSF (CA) Washington University (MO) John Hopkins (BC)
Funding: Medtronic Sofamor Danek
Date: June 2004-Ongoing

There are concerns about complications associated with anterior exposure for the spine, especially in cases of multilevel exposure in spinal deformity. Little is written about the prevalence or severity of specific problems like pseudohernia, incisional pain, and visceral injury. Additionally, anterior approaches more directly affect the anterior view of the torso which is what patients see (while physicians most often look at the posterior view), and therefore these approaches may have more impact on cosmesis and self image which are important issues in deformity.

Dr. Ondra (PI at NU) is an active member in the Scoliosis Research Society and performed surgery on all subjects involved.

Attachment B

From: Hawkins, William [REDACTED]
Sent: Friday, January 16, 2009 4:22 PM
To: La Neve, Steve
Cc: Carlson, Terry [General Co]; Gorsuch, Kirsten; Slone, Peter
Subject: Dr. Ondra

I spoke this afternoon with Dr. Casscells, current Assistant Secretary of Defense for Health Affairs, regarding the process by which we might recommend a candidate to replace him in the new administration. I have known Dr. Casscells for many years and was comfortable in approaching him on

Confidential [REDACTED]

this topic.

He welcomed my call and indicated that recommendations from CEOs were very important. Dr. Casscells indicated that the decision to replace him would be made by Secretary of Defense, Robert Gates, and the President of the United States. Dr. Casscells suggested that I write a letter to Secretary Gates recommending Steve Ondra. Dr. Casscells knows of Dr. Ondra. In fact, he is planning to have coffee with him next week.

Steve, I would appreciate you drafting a letter for me to send on behalf of Dr. Ondra underscoring some of his accomplishments, which would endorse his nomination. I would like to send this letter to Secretary Gates early next week. In the draft, you should note that I respect and admire Dr. Ondra for his integrity, his honor and duty to this country, and his extraordinary accomplishments as an esteemed surgeon.

If you have any questions, please let me know.

Bill

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Attachment C

Positions of Interest in the Obama-Biden Administration
for
Stephen L. Ondra, MD

1. DEPARTMENT OF DEFENSE

Assistant Secretary of Defense for Health Affairs

2. DEPARTMENT OF VETERANS AFFAIRS

VHA

Under Secretary for Health

Principal Deputy Under Secretary for Health

3. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administrator, Centers for Medicare and Medicaid Services

Director, Office of Policy

4. Food and Drug Administration

Commissioner of the Food and Drug Administration

Special Assistant to the Commissioner of the FDA