Minutes for Spine Section Executive Committee Meeting
March 07, 2012
Orlando, FL

Members Present:

The meeting was called to order by Dr. Wolfla at 08:00

1. Secretary's report P. Mummaneni
    a. Update of email list and contact info
    b. Review and approval of minutes
    c. Review EC grid
    d. Informational items
        - Section Support of NREF (*)
        - STASCIS (*)
        - SPC report- Marjorie Wang (*)
2. Treasurer's Report J. Hurlbert
    a. Review and approve budget (*)
    b. Review Annual meeting reconciliation
3. New Business
4. Old Business
5. Committee Reports
    a. Annual Meeting D. Fournay
    b. CPT J. Cheng, J Knightly
    c. Exhibits Mike Wang
    d. Future sites I. Kalfas, E. Woodard
    e. Research and Awards A. Kanter
        - Regis Haid Spinal Deformity Award update
    f. Education Frank LaMarca
    g. Guidelines M. Kaiser
    h. Outcomes Z. Ghogawala
    i. Peripheral nerve TF A. Belzberg
        - Discuss coding issues and grant submissions
    j. Publications L. Holly
    k. Public Relations M. Steinmetz
    l. Membership P. Angevine
    m. Washington Committee R. Heary (K. Orrico)
    n. Fellowships G. Trost/Marjorie Wang
    o. Web Site E. Potts
    p. CME C. Sansur
    q. Nominating Committee C. Shaffrey
    r. Rules and Regs J. Smith
        - Addition of RRC (Rapid Response Committee)
    s. Newsletter M. Steinmetz, K. Eichholz
    t. ASTIM J Coumans
    u. NREF Z. Gokoslan, E. Woodard

v.	AANS PDP	K. Foley, P. Johnson
w.	Young Neurosurgeons comm.	C. Upadhyaya
x.	FDA drugs and devices	J. Alexander
	• Update attached (*)	
y.	Inter-Society Liaison	M. Rosner
z.	Spinal Deformity training	P. Mummaneni

There being no further business the meeting was adjourned at Noon.

Respectfully submitted, Praveen Mummaneni, Secretary.

2012 DSPN VIP
As of 2/1/2012

Sal	First Name	MI	Last Name	Position
Dr.	Joseph		Alexander	FDA Drugs & Devices
Dr.	Peter	D.	Angevine	Ad Hoc Committee for NeuroPoint Alliance, Membership Committee Chair
Dr.	J. Patrick	Brad	Bellotte	Young Neurosurgeons Representative
Dr.	Allan		Belzberg	Peripheral Nerve Task Force Chair
Dr.	Joseph	S.	Cheng	Chair-Elect, Ad Hoc Committee for Policy/Procedure
Dr.	John		Chi	Research & Awards Committee
Dr.	Jean Valery		Coumans	ASTM
Dr.	Sanjay		Dhall	Publications Committee Chair
Dr.	Kurt	M.	Eichholz	Newsletter Chair
Dr.	Kevin	T.	Foley	AANS PDP Representative
Dr.	Daryl	R.	Fourney	Annual Meeting Chair
Dr.	Kai	M.	Fu	Rapid Response task Force
Dr.	Zoher		Ghogawala	Ad Hoc Committee for Policy/Procedure, Outcomes Committee Chair
Dr.	Ziya	L.	Gokaslan	Immediate Past Chair, Section Rep., P.A.C., NREF Advisory Board, Nominating Chair Committee
Dr.	Michael	W.	Groff	Member at Large, Washington Committee
Dr.	Kojo		Hamilton	Rapid Response task Force
Dr.	Robert	F.	Heary	Washington Committee
Dr.	Daniel		Hoh	Exhibit Chair
Dr.	Langston	T.	Holly	Fellowships Chair, Publications Committee Chair
Dr.	R. John		Hurlbert	Treasurer
Dr.	J. Patrick		Johnson	AANS PDP Representative
Dr.	Michael	G.	Kaiser	Guidelines Committee Chair
Dr.	Iain	H.	Kalfas	Future Sites Chair
Dr.	Adam		Kanter	Research & Awards Committee Chair
Dr.	John	J.	Knightly	Ad Hoc Committee for Policy/Procedure, Washington Committee
Dr.	Charles		Kuntz, IV	Member-at-Large
Dr.	Frank		La Marca	Education Committee Chair
Dr.	Daniel		Lu	Research & Awards Committee
Dr.	Praveen	V.	Mummaneni	Secretary, Ad Hoc Committee for NeuroPoint Alliance
Dr.	David	O	Okonkwo	Rapid Response task Force
Dr.	Eric	A.	Potts	Web Site Committee Chair
Dr.	John		Ratliff	Rapid Response task Force
Dr.	Daniel	K.	Resnick	Ad Hoc Committee for Policy/Procedure
Dr.	Michael	K.	Rosner	Inter-Society Liaison
Dr.	Charley		Sansur	Rapid Response task Force
Dr.	Daniel		Scuibba	Ad Hoc Committee for NeuroPoint Alliance, Exhibits
Dr.	Justin		Smith	Rules & Regulations Chair
Dr.	Michael	P.	Steinmetz	Public Relations
Dr.	Brian		Subach	Ex-Officio Member
Dr.	Gregory	R.	Trost	Ad Hoc Committee for Policy/Procedure, AMA Impairment
Dr.	Luis		Tumialan	Rapid Response task Force
Dr.	Cheerag		Upadhyaya	Young Neurosurgeons Representative
Dr.	Michael		Wang	Exhibit Chair
Dr.	Marjorie	C.	Wang	Scientific Program Chairperson, Fellowships Chair
Dr.	Christopher	E.	Wolfla	Chair, CNS President
Dr.	Eric	J.	Woodard	Future Sites Chair, NREF Advisory Board
Dr.	Eric	L.	Zager	Member at Large

2012 DSPN VIP
As of 2/1/2012

Last Name	Email
Alexander	jtalexan59@yahoo.com
Angevine	pda9@columbia.edu
Bellotte	bradbellotte@gmail.com
Belzberg	belzberg@jhu.edu
Cheng	joseph.cheng@vanderbilt.edu
Chi	jchi@partners.org
Coumans	jcoumans@partners.org
Dhall	sanjaydhall@yahoo.com
Eichholz	kurt@eichholzmd.com
Foley	kfoley@usit.net
Fourney	daryl.fourney@usask.ca
Fu	
Ghogawala	zoher.ghogawala@lahey.org
Gokaslan	zgokasl1@jhmi.edu
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Heary	heary@umdnj.edu
Hoh	daniel.hoh@neurosurgery.ufl.edu
Holly	lholly@mednet.ucla.edu
Hurlbert	jhurlber@ucalgary.ca
Johnson	johnsonjp@cshs.org
Kaiser	mgk7@columbia.edu
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Kanter	kanteras@upmc.edu
Knightly	jknightly@atlanticneurosurgical.com
Kuntz, IV	charleskuntz@yahoo.com
La Marca	flamarca@med.umich.edu
Lu	Daniel.C.Lu@gmail.com
Mummaneni	vmum@aol.com
Okonkwo	okonkwodo@upmc.edu
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Ratliff	
Resnick	resnick@neurosurgery.wisc.edu
Rosner	michael.rosner@us.army.mil
Sansur	csansur@gmail.com
Scuibba	dsciubb1@jhmi.edu
Smith	jss7f@virginia.edu
Steinmetz	msteinmetz@metrohealth.org
Subach	brsubach@spinemd.com
Trost	trost@neurosurgery.wisc.edu
Tumialan	
Upadhyaya	cheerag.upadhyaya@gmail.com
Wang	mwang2@med.miami.edu
Wang	mwang@mcw.edu
Wolfla	cwolfla@mcw.edu
Woodard	ewoodard@caregroup.harvard.edu
Zager	zagere@uphs.upenn.edu

Executive Committee
Officers and Committee Chairs
JOINT SECTION ON DISORDERS OF THE SPINE & PERIPHERAL NERVES
2012

Position	2007-2008	2008-2009	2009-2010	2010-2011	2011-212
Chair	J. Alexander	D. Resnick	C. Shaffrey	Z. Gokaslan	C. Wolfla
Chair Elect	D. Resnick	C. Shaffrey	Z. Gokaslan	C. Wolfla	J. Cheng
Immediate Past Chair	C. Branch	J. Alexander	D. Resnick	C. Shaffrey	Z. Gokaslan
Secretary	D. Resnick	M. Groff	M. Groff	M. Groff	P. Mummaneni
Treasurer	C. Wolfla	C. Wolfla	J. Hurlburt	J. Hurlburt	J. Hurlburt
Members at Large	K. Foley G. Trost C. Shaffrey	G. Trost M. McLaughlin E. Zager	C. Wolfla M. McLaughlin E. Zager	M. McLaughlin E. Zager C. Kuntz	E. Zager C. Kuntz M. Groff
Ex-Officio Members	R. Haid E. Woodard P. Johnson	J. Hurlbert J. Knightly	C. Kuntz F. LeMarca D Okonkwo	F. LeMarca D Okonkwo	B Subach
Annual Meeting Chair	J. Hurlbert	C. Kuntz	P. Matz	P. Mummaneni	D Fournay
Scientific Program Chair	C. Kuntz	P. Matz	P. Mummaneni	D Fournay	Marj Wang
Exhibit Chair	J. Knightly P. Mummaneni	P. Mummaneni	B. Subach	B. Subach	Mike Wang D. Sciubba D Ho
Future Sites	I. Kalfas	I. Kalfas P. Mummaneni	I. Kalfas E. Woodard	I. Kalfas E. Woodard	I. Kalfas E. Woodard
Education Committee Chair	M. Groff P. Matz	Mike Wang	Mike Wang	Mike Wang	F LaMarca
CME Representative	E. Mendel	E. Mendel	D. Fournay	Marg. Wang	C. Sansur
Newsletter	M. Groff	M. Steinmetz K. Eichholz	M. Steinmetz K. Eichholz	M. Steinmetz K. Eichholz	K. Eichholz
Rules and Regulations Chair	T. Choudhri	T. Choudhri	T. Choudhri	T. Choudhri	J Smith
Nominating Committee Chair	C. Branch	J. Alexander	D. Resnick	C. Shaffrey	Z Gokaslan
Research and Awards Committee Chair	P. Gerszten	P. Gerszten	Marg. Wang P. Gerszten A. Kanter	Marg. Wang A. Kanter D. Scubbia	A. Kanter J. Chi D. Lu
Publications Committee Chair	M. Wang	L. Holly	L Holly	L Holly	L. Holly S. Dahl
Web Site Committee Chair	J. Cheng	J. Cheng	E. Potts J. Cheng	E. Potts J. Cheng	E. Potts
Guidelines Committee Chair	P. Matz M. Kaiser	M. Kaiser	M. Kaiser	M. Kaiser	M. Kaiser
Membership Committee	Z. Gokaslan Marg. Wang	Marg. Wang	P. Angevine	P. Angevine	P. Angevine
Outcomes Committee Chair	M. Kaiser Z. Ghogawala	Z. Ghogawala	Z. Ghogawala	Z. Ghogawala	Z. Ghogawala
CPT Committee	J. Cheng	J. Cheng	J. Knightly	J. Knightly	J. Knightly P. Angivine
Peripheral Nerve Task Force Chair	E. Zager	A. Maniker	A. Maniker	R. Spinner	R. Spinner

Washington Committee	J. Alexander/R. Heary	R. Heary	R. Heary	R. Heary	R. Heary J.Knightly M. Groff
FDA drugs and devices		J. Alexander	J. Alexander	J. Alexander	J. Alexander
Section Rep.,P.A.C.	Z. Gokaslan	Z. Gokaslan	Z. Gokaslan	Z. Gokaslan	Z. Gokaslan
Public Relations	M. Steinmetz	M. Steinmetz	M. Steinmetz	M. Steinmetz	M. Steinmetz
Fellowships	P. Mummaneni	P. Mummaneni	G. Trost	G. Trost	M. Wang L Holly
NREF Advisory Board	J. Guest	Z. Gokaslan E. Woodard	Z. Gokaslan E. Woodard	Z. Gokaslan E. Woodard	Z Gokaslan E. Woodard
AANS PDP Representative	M. Groff	P. Johnson K. Foley	P. Johnson K. Foley	P. Johnson K. Foley	P. Johnson K. Foley
Young Neurosurgeons Representative	H. Aryan	E. Potts D. Sciubba	E. Potts D. Sciubba	E. Potts D. Sciubba	Upadhyaya
AMA Impairment	G. Trost	G. Trost	G. Trost	G. Trost	G Trost
ASTIM	G. Trost	G. Trost	J. Coumans	J. Coumans	J Coumans
Inter- Society Liaison	S. Ondra M. Rosner	M. Rosner	M. Rosner	M. Rosner	M Rosner
Ad hoc Comm for Policy/Procedure for Payer Policy Responses			J. Cheng J. Knightly Z. Ghogawala G. Trost D. Resnick	J. Cheng J. Knightly Z. Ghogawala G. Trost D. Resnick	J. Cheng J. Knightly Z. Ghogawala G. Trost D. Resnick
Ad hoc Comm for NeuroPoint Alliance Modules			P. Matz J. Smith Than Brooks D. Scuibba	P. Matz J. Smith Than Brooks D. Scuibba	P. Matz J. Smith Than Brooks D. Scuibba

American Association of Neurological Surgeons

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February 7, 2012

R. John Hurlbert, MD PhD
Foothills Med. Ctr./Clinical Neurosci.
1403 29th St. N.W. Rm. C 1249
Calgary, AB T2N-2T9
Canada

Dear Doctor Hurlbert:

The enclosed financial statements for the AANS/CNS Section on Disorders of the Spine and Peripheral Nerves are for the six months ended December 31, 2011, and comparative information for the six months ended December 31, 2010.

After your review of the financial statements and commentary, if you have any questions, please do not hesitate to contact me at 847-378-0561 or rpc@aans.org.

Sincerely,

Rebecca P. Calloway-Blyth
Section Accountant

Enclosures

Cc: Christopher Wolfla, MD
Paul C. McCormick, MD
Robert E. Harbaugh, MD FACS
Russell R. Lonser, MD
Ronald W. Engelbreit
Regina Shupak

AANS/CNS Section on Disorders of the Spine
Statement of Financial Position
As of December 31, 2011

	Current Year 12/31/11	Prior Year 12/31/10
ASSETS		
Checking & Short Term Investments	$664,197	$440,345
Accounts Receivable, net of Allowance for Uncollectible Accounts	32,500	32,858
Long-Term Investment Pool, at Market	2,386,762	2,341,510
TOTAL ASSETS	$3,083,460	$2,814,713
LIABILITIES AND NET ASSETS		
Liabilities		
Accounts Payable and Current Liabilities	$80,000	$25,000
Deferred Dues	50,600	47,100
Total Liabilities	**$130,600**	**$72,100**
Net Assets		
Unrestricted	$2,985,837	$2,574,745
Unrestricted - Fellowships	$52,000	$50,000
Net Revenue (Expense)	(84,978)	117,868
Total Net Assets	**$2,952,860**	**$2,742,613**
TOTAL LIABILITIES AND NET ASSETS	$3,083,460	$2,814,713

AANS/CNS Section on Disorders of the Spine
Statement of Activities
For the Six Months Ending December 31, 2011

	FY '10 Final	FY '11 Final	YTD FY '12	FY '12 Budget
REVENUES				
Membership Dues	$52,550	$52,903	$21,247	$50,400
Mailing List Sales	1,180	885	690	0
Fellowship/Award Sponsorship	125,000	205,000	6,895	161,000
Miscellaneous Revenue	0	104	0	0
Contributions for Operating Expenses	7,893	8,439	2,917	9,237
Annual Meeting Revenue	1,037,804	959,225	0	1,015,500
TOTAL REVENUES & SUPPORT	$1,224,427	$1,226,556	$31,749	$1,236,137
EXPENSES				
Audio Visual	$1,499	$1,724		$2,000
Bank Fee	470	604	203	691
Contributions & Affiliations	187,500	75,000	1,500	100,000
Decorating	607	540	0	550
Food & Beverage	3,994	5,914	800	6,000
Honoraria & Awards	188,497	186,273	15,000	195,075
Office & other Supplies	135	335	220	500
Photocopy	1	2	2	25
Postage & Distribution	1,146	1,073	722	1,500
Printing/Typesetting	0	7	0	0
Staff Travel	0	0	0	225
Telephone	30	143	54	200
Volunteer Travel	0	19,966	0	6,500
Website	436	908	0	12,500
Staff Coordination	7,893	8,439	2,917	9,237
Miscellaneous	0	7,500	410	0
Guidelines Development	10,010	4,420	20,273	50,000
Spine Section History Project	15,952	0	0	0
Annual Meeting Expense	657,634	676,514	50,000	655,344
TOTAL EXPENSES	$1,075,804	$993,782	$92,101	$1,040,347
Investment Earnings	120,394	175,898	(24,624)	108,200
NET REVENUE	$269,017	$408,672	($84,976)	$303,990

Sponsorship Update - 12/31/11
Spine Section

Budgeted Sponsorships:		Budgeted Amount	Date Received	Amount Received	
H. Alan Crockard Int'l Fellowship	DePuy Spine	$5,000.00			
Sanford Larson Research Award	DePuy Spine	$30,000.00			
Ronald Apfelbaum Research Award	Aesculap	$15,000.00			Application Submitted to Aesculap
David Cahill Fellowship	Synthes	$30,000.00			
David Kline Research Award	Integra	$15,000.00			Application Submitted to Integra
David Kline Lectureship	Integra	$5,000.00			Application Submitted to Integra
Clinical Trials Fellowship Award	Greenwich Hospital	$23,000.00			
Ralph Cloward Fellowship	Medtronic	$30,000.00			
Sonntag International Fellowship	Medtronic	$5,000.00			
David Kline Lectureship Dinner	Integra	$3,000.00			
Total Received in FY12				$ -	
Unexpended Kline Research Award Funds Returned	W. Ray		7/19/2011	$ 6,894.72	

Scientific Program Committee report

- SPC meetings: minutes, attendance, poster committee members
    - Phone conferences with CNS CME committee: presenter, committee, presentations bias; 1/12/12 and 2/15/12
        - Approximately 53% presentations received at time of this report
    - Pre and Post Course assessment (CME)
        - Special Course III – Spinal Deformity
        - Special Course VIII - Peripheral Nerve Exposures and Nerve Repair Techniques
        - Luncheon Symposium III – Cranial Cervical Junction
- Attendance
    - Advance registration: 343 medical attendees
        - 2% more than last Orlando meeting
        - 5% less than 2011 Phoenix meeting
    - Member attendance
        - 18% more than 2011
        - 13% more than 2010
    - Nass and Non-Member registrants decreased

2012 AANS/CNS Section on Disorders of the Spine and Peripheral Nerves Annual Meeting
Advanced Registration Comparison

										Monday	Monday	Monday	Thursday
Description	12/23/2009	1/19/2011	1/11/2012	12/30/2009	1/26/2011	1/18/2012	1/6/2010	2/2/2011	1/25/2012	2/9/2009	1/11/2010	2/7/2011	**2/2/2012**
	3 Weeks to Cut-off			**2 Weeks to Cut-off**			**1 Week to Cut-off**			**Cut-off**			
	2010	**2011**	**2012**	**2010**	**2011**	**2012**	**2010**	**2011**	**2012**	**2009**	**2010**	**2011**	**2012**
Spine Section Member	87	132	82	99	151	117	124	170	151	179	183	176	208
NASS Member	19	15	6	20	23	6	24	25	6	19	28	30	14
Orthopedic Surgeon	1	4	1	1	4	1	2	5	2	3	3	6	3
Nonmember	16	19	19	19	25	25	31	36	27	58	51	57	48
Non-Physician, Nonmember	2			2	1		3	3	1		5	4	1
Nurse	1	4	2	1	4	2	3	5	5	12	4	8	6
Physician Assistant	4	4	2	4	4	4	6	7	5	14	10	13	10
Resident	34	26	12	35	30	14	40	31	25	50	48	40	39
Medical Student	2	6	5	2	7	6	3	7	6		4	9	8
Non-Member Faculty		14	2		15	3		16	5			19	6
Total Medical Attendees	**166**	**224**	**131**	**183**	**264**	**178**	**236**	**305**	**233**	**335**	**336**	**362**	**343**
Guests/Child	27	29	19	32	41	45	44	45	54	80	66	47	79
Total Registrants	**193**	**253**	**150**	**215**	**305**	**223**	**280**	**350**	**287**	**415**	**402**	**409**	**422**

Scientific Program Committee Meeting 10/2/11
Minutes (mw)

I. Call to order
II. Attendance
III. Committee Issues
    a. Review/update of disclosures
    b. Planning committee recused if any conflicts
    c. Review of CNS mission statement
    d. Discussion of adjudication of slides/presentations and reviews for bias
        i. Issues from CNS Education committee
            1. HIPAA violations
            2. Copyright issues from snapshots of published work
IV. Summary of changes 2010 to 2011 meeting
V. Review of program grids
    a. Responsibilities of moderator
        i. Each moderator to receive a script to announce strict timekeeping of talks at beginning of each session
        ii. MW/DF in audience to help keep time; slides and microphone will be turned off at end of allotted speaker time
    b. Discussion of gaps in speaker acceptances
        i. S.Dhall to contact Rodts
        ii. Attempt to contact nonrespondents at EC meeting
        iii. Young Neurosurgeon's Dinner guest
        iv. Hadley to discuss guidelines/quality on Thursday
    c. Dr. Belzberg notes lack of peripheral nerve in title of meeting
        i. CNS office contacted to revise meeting name to: Spine and Nerve Surgery
    d. Saturday morning audience participation
        i. Logistics discussed
        ii. Case presentations by C.Sansur and Wale
        iii. SPC members to be assigned to help get discussion going and stimulate audience participation
VI. Abstract grading
    a. Due 10/8/11
    b. Concern over lack of disclosures noted in abstract submission
        i. Graders to comment if suspicion of bias but no disclosures mentioned
    c. Phone conference to follow to finalize award winners, any other issues
    d. Discussants to be selected after presentations finalized

Attendance
Scientific Program Committee Meeting

Name	e-mail address	Attended March 2011	Attended April 11, 2011	Attended Oct 2, 2011	Attended Oct 18, 2011
Pete Angevine	pda9@columbia.edu			√	Excused
Allan Belzberg	belzberg@jhu.edu			√	Excused
Ali Bydon	abydon1@jhmi.edu		√		
John Chi	jchi@partners.org	√	√	√	√
Dean Chou	choud@neurosurg.ucsf.edu	√	√	√	√
Sanjay Dhall	sanjaydhall@yahoo.com	√	√	√	√
Daryl Fourney-Ann Program Chair	Daryl.Fourney@usask.ca	√		√	√
Aruna Ganju	aganju@nmff.org	√			√
Jim Harrop	james.harrop@jefferson.edu	√	√		
Langston Holly	lholly@mednet.ucla.edu		√	√	
Patrick Hsieh	phsieh@usc.edu	√	√		Excused
Jack Knightly	knightly@atlanticneurosurgical.com	√			
Shekar Kurpad	skurpad@mcw.edu	√		√	√
Frank LaMarca	flamarca@med.umich.edu	√	√	√	
Daniel Lu	daniel.c.lu@gmail.com	√	√		√
Mike Martin	Michael-Martin@ouhsc.edu	√			Excused
Matthew McGirt	matt.mcgirt@vanderbilt.edu	√			√
David Okonkwo	okonkwodo@upmc.edu		√	√	
Srini Prasad	srinivas.prasad@jefferson.edu	√	√		
Charles Sansur	csansur@gmail.com	√	√		
Meic Schmidt	meic.schmidt@hsc.utah.edu	√			√
Justin Smith	JSS7F@virginia.edu	√		√	√
Robert Spinner	Spinner.Robert@mayo.edu	√	√		√
Michael Steinmetz	spinemetz@yahoo.com	√			√

Attendance
Scientific Program Committee Meeting

Name	e-mail address	Attended March 2011	Attended April 11, 2011	Attended Oct 2, 2011	Attended Oct 18, 2011
Andrea Strayer	strayer@neurosurgery.wisc.edu				Excused
Wale Sulaiman	wsulaiman@ochsner.org	√			
Eve Tsai	etsai@Ottawahospital.on.ca	√		√	√
Marjorie Wang-SPC Chair	mwang@mcw.edu	√	√	√	√
Christopher Wolfla	cwolfla@mcw.edu			√	√
Jean-Paul Wolinsky	jwolins3@jhmi.edu	√		√	√
Lynda Yang	ljsyang@med.umich.edu	√			

Poster Committee

Jack Knightly

Srini Prasad

Sanjay Dhall

Adam Kanter

Outcomes Committee Report
Spine Section Executive Committee Meeting
Wednesday, March 7, 2012
Walt Disney World Swan and Dolphin
Orlando, Florida

Committee Members:
Zoher Ghogawala, zoher.ghogawala@yale.edu (chair)
Daniel Hoh, daniel.hoh@neurosurgery.ufl.edu (vice-chair)
Subu N.Magge, subu.n.magge@lahey.org
John O'Toole, John_Otoole@rush.edu
Jean-Valery Coumans, jcoumans@partners.org

A. NEUROPOINT-SD Funded $ 200,000

Primary Aim: To establish a multi-center clinical research group that demonstrates 80% compliance in collecting 1 year outcomes data for the surgical treatment of lumbar spinal disorders
Secondary Aim: To demonstrate clinical effectiveness for the surgical treatment of two common spinal disorders: lumbar disc herniation and lumbar spondylolisthesis

Design – Prospective outcomes study – 200 patients (10 centers)
Outcome – SF-12, VAS, ODI (pre-op, 1,3,6,12 months)

Enrollment Completed. Presentation at Spine Section and at AANS Meeting

Results:

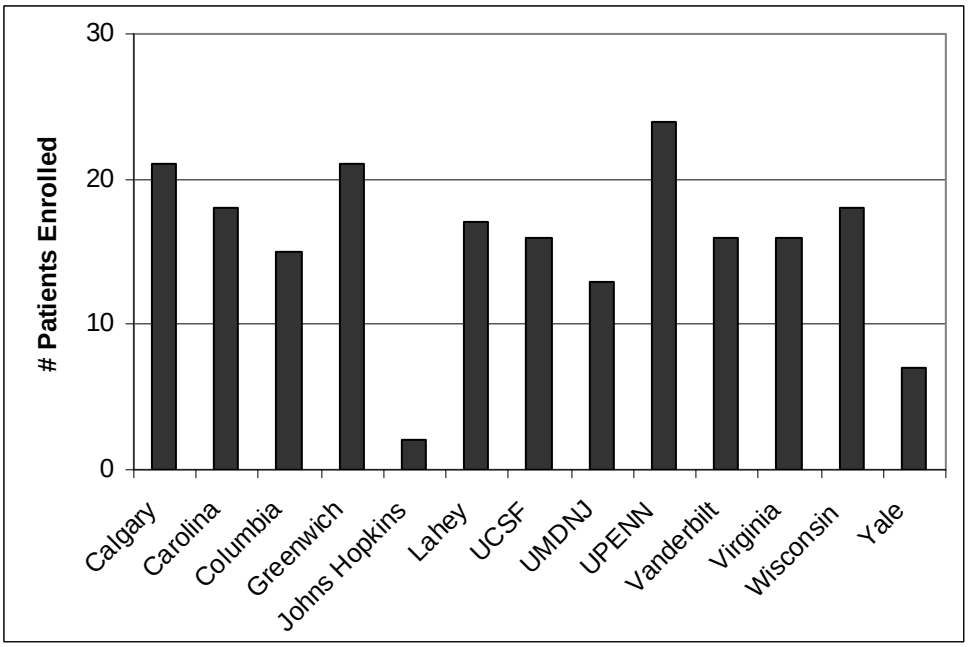
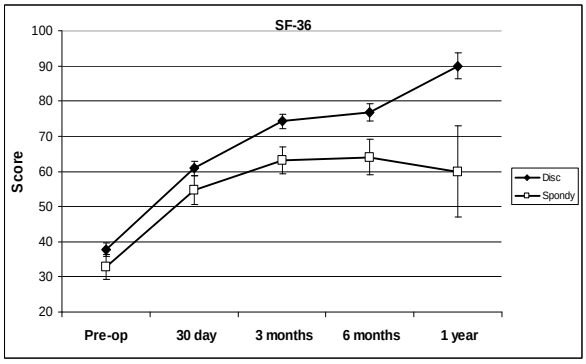


Figure 1. Total number of patients enrolled by site. Enrollment goal was 10 pts/site. Mean = 16 pts/site. Range 2-24 pts/site.

A.



B.

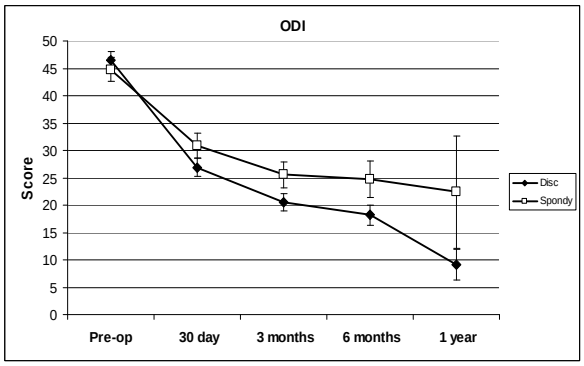


Figure 2. Outcomes assessment over 1 year time period. (A). Improvement in SF-36 physical function over time for lumbar discectomy (N=156) and

single level fusion for lumbar spondylolisthesis (N=48) (P<0.001; both groups). (B). Reduction in ODI over time for lumbar discectomy and for single level fusion for lumbar spondylolisthesis (P<0.001; both groups).

B. Clinical Trials Proposal Awards $ 500 (advertised by E-Blast)

1. We received 5 clinical trial proposals from 5 different institutions that met all requirements. All competitive trial proposals were reviewed by at least 3 reviewers from the committee and NIH scoring criteria were followed. Proposals were reviewed according to:

   a) significance
   b) design and approach
   c) innovation
   d) overall potential to have impact on clinical care

   The scores of all three reviewers were averaged and placed into a grid. All proposals were reviewed by 3 separate reviewers and the scores averaged. Two proposals had clearly superior scores. The third was selected over a conference call by blinded reviewers based on the potential impact factor of the project.

   The three top proposals were:

   Bradley Jacobs, MD (Faculty)
   University of Calgary
   "Mean arterial pressure in spinal cord injury (MAPS): Determination of non-inferiority of a mean arterial pressure goal of 65 mm Hg compared to a mean arterial pressure goal of 85mmHG in acute human traumatic cervical spinal cord injury."
   Design – single center, RCT, 140 subjects
   Outcome – ASIA motor score, FIM, SCIM, SF-36
   Scientific Principle – Neurologic outcomes after acute traumatic spinal cord injury are equivalent whether treated with mean arterial pressure elevation > 85 mmHg or > 65 mm Hg.

   Jefferson Wilson, MD (Resident), Michael Felhings MD, PhD (Supervising Faculty)
   University of Toronto
   "Riluzole in Acute Spinal Cord Injury (RISCIS): A multicenter placebo controlled randomized trial."
   Design – multicenter, RCT, 284 subjects
   Outcome – ASIA Motor Score, SCIM

Scientific Principle – Neuroprotection after acute traumatic spinal cord injury with riluzole, a benzothiazole anticonvulsant, results in better long term neurologic outcome than placebo.

Sanjay Dhall, MD (faculty)
Emory University
"Intraoperative electrophysiological monitoring in the surgical management of cervical spondylotic myelopathy"
Design: multicenter, comparative study, 120 subjects
Outcome: modified JOA score, visual analogue score, complication
Scientific Principle – Use of intraoperative monitoring compared to no monitoring during surgical treatment of cervical spondylotic myelopathy does not improve clinical outcomes.

B. Clinical Trials Award – $ 50,000

The Outcomes Committee will review all three revised clinical trial proposals and score each of them. Revised proposals are due July 1, 2012.

The three proposal winners will have 3 months to work with the Outcomes committee to improve their proposal. All will submit their proposal for consideration for the $50,000 clinical trials award and for the NREF award. The clinical trials award will be given in 2 parts: $25,000 initially once a satisfactory letter from a biostatistician has been received. The second $25,000 will be awarded once a progress report has been received summarizing progress on each of the specific aims listed in the grant proposal. The second $25,000 will be awarded only if 50% of the proposal accrual has been reached.

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2). Previous Clinical Trials Award Winners: (updates from each award winner will be presented at this meeting).

2008 Winner
Khalid Abbed, MD, Yale University, Assistant Professor
Proposal: To compare minimally invasive T-LIF versus open T-LIF for grade I spondylolisthesis with symptomatic spinal stenosis.
Design: pilot study - 100 pts, 3 sites, non-randomized.
Outcome Instruments: SF-36 PCS and ODI

2009 Winner
Marjorie Wang, MD, MPH, Medical College of Wisconsin, Assistant Professor
Proposal: To determine if pre-operative diffusion tensor imaging might predict post-surgical outcome following surgery for CSM
Design: pilot study: 83 patients, single site, non-randomized
Outcome Instruments: mJOA (6 months) – MCID = 2 points

2010 Winner
Basheal Agrawal, MD (resident) – Daniel Resnick (faculty sponsor)
Medical College of Wisconsin (institution)
Proposal: "Development of a web-based registry for evaluating the comparative effectiveness of various treatments for low back pain in Wisconsin"
Design: Prospective Single Center Study to evaluate feasibility of comparative effectiveness study
Outcome: Oswestry (ODI), Visual Analog Scale (VAS).
Scientific Principle – Development of a prospective outcomes database platform for measuring spine outcomes is feasible

C. Spine Section Web Site

In addition, we are keeping the section website current with a section on all active clinical trials registered with the NIH site clinicaltrials.gov that relate to spinal diseases. There are currently 153 clinical trials relating to spinal disorders registered with ClinicalTrials.gov – all are listed on our section website.

American Association of Neurological Surgeons
and the American Association of Neurosurgeons

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Neurosurgery Research and Education Foundation

Thirty Years of Advancing Neurosurgery through Research

October 25, 2011

Christopher Wolfla, MD, FAANS
Chair, AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
Medical College of Wisconsin
Dept. of Neurosurgery
9200 W. Wisconsin Ave.
Milwaukee, WI 53226-3522

Dear Chris,

On behalf of the American Association of Neurological Surgeons (AANS) and the Neurosurgery Research and Education Foundation (NREF), we send our sincere appreciation for the support of the NREF from the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves.

We also want to share with you the results of this support. Over the past five (5) years, the NREF received 51 applications focused on spine and peripheral nerves; 17 of these have been funded – 12 research fellowships and five (5) young clinician investigator awards.

We are inviting each Section to participate in the review and selection process for the 2012-2013 academic year research grants (for which applications are due October 31st, 2011). Participation by the AANS/CNS Section on Pediatrics last year resulted in a tripling of applications related to pediatrics and 2 of the 10 awards were for research related to Pediatric neurosurgery. We anticipate that an analogous process will have a similar effect on interest from other subspecialties.

Applications are due October 31st; after its initial administrative review, the NREF's Scientific Advisory Committee (SAC) would forward to the Section the 8-10 most highly rated spine-related applications, likely in December 2011. An internal grants committee, designated by the Section could review these and identify its top three (3) choices for the SAC Chair, Edward Oldfield, MD by mid-January 2012; he would then share this information with the entire SAC when the committee meets in February 2012 to review all applications and make its funding determinations. Would the Spine Section be interested in participating in this way?

Finally, the NREF is encouraging each Section's Executive Council members to lead by example and join the Cushing Circle of Giving. In 2008, the NREF established a program that is a cumulative, lifetime and planned/deferred giving society for individuals who support the NREF. The goals of the NREF Cushing Circle include increasing NREF giving (annual, major and planned gifts), creating an organizational identity, and building camaraderie among philanthropists who consistently support the NREF. Criteria for individual membership include: historical giving total of at least $20,000; historical giving total of at least $10,000, with a pledge of at least $10,000 within the next five years (at a minimum rate of $2,000 per year); or historical giving total of at least $10,000, with a memorandum of understanding for a willed bequest of at least $50,000.

Thanks in part to the efforts of a number of key neurosurgical leaders, 11 new members were added this year, bringing the total participants to 32. Current benefits of participation include special invitations to events at the AANS Annual Meeting and special recognition online and in AANS publications. New benefits for participation are being considered for 2012 including an ad on the AANS Annual Meeting app, recognition with special decal on annual meeting name badge, earlier pre-booking of your hotel stay at the headquarters hotel for the 2012 AANS Annual Meeting in Miami and special amenities upon arrival and departure for guests staying at the AANS Annual Meeting headquarters hotel.

We hope that the Spine Section will continue its support of the NREF and participate in the selection of awardees and that you and the Section's other leaders will join the Cushing Circle.

Best personal regards,

Griffith R. Harsh, IV, MD, FAANS
Chair, NREF Executive Council
& 1986 NREF research grant recipient

Paul C. McCormick, MD, FAANS
President, 2011-2012 AANS Board of Directors

CC: Joseph Cheng, MD, FAANS, Chair-elect
Ziya Gokaslan, MD, FAANS, FACS, Past-Chair
Praveen Mummaneni, MD, FAANS-Secretary
R. John Hurlbert, MD, PhD, FAANS, FRCSC, FACS-Treasurer

DRUGS AND DEVICES UPDATE

Physician/Industry Relations

Sunshine Act Proposed Regulations Released

On December19, 2012, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule entitled *Transparency Reports and Reporting of Physician Ownership or Investment Interests* that would implement provisions of the Physician Payment Sunshine Act (Section 6002 of the Affordable Care Act), mandated as part of the Affordable Care Act (ACA). The ACA provides that beginning in 2012, manufacturers of a drug, device, biological or medical supplies participating in U.S. federal health care programs must begin tracking any transfers of value or payments exceeding $10 to physicians and/or teaching hospitals. These reports must be submitted to the Secretary of Health and Human Services (HHS) on an annual basis. The majority of the information contained in the reports will be available on a public, searchable website in 2013, when the transfers of value cumulatively exceed $100

The American Medical Association (AMA) held a briefing for specialty society staff with CMS staff on the issue on January 24, 2012. At the briefing, CMS staff would not answer specific questions on indirect transfers--claiming they could not with the comment period open. However, AMA staff said their reading of the rule leads them to believe CMS has gone beyond the intention of Congress on the indirect transfer issue. The legislation originally written in the ACA had excluded third parties from having to disclose indirect payments to "covered recipients" (physicians or other healthcare professionals) by "applicable manufacturers" (drug and device companies). Payments to faculty of CME supported by industry fell under this exclusion. However, the proposed rule which would require companies to report any commercial support money that they become aware of having indirectly benefitted faculty or attendees, could put the burden on CME providers to track the third party recipients of commercial support. The CME providers could be asked to provide the manufacturers with names of individuals who benefited from the indirect payment.

The AMA is drafting a sign on letter that they will circulate soon. In addition, the Alliance of Specialty Medicine is developing a letter on the issue. The letters will ask that CMS adhere to the very narrow language of the statute. The proposed rule is available on the CMS website at: http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf

Congressional Activity

Congressional Hearings on FDA User Fee Reauthorization

The FDA and Industry have completed negotiations on user fees and forwarded then to Congress. Congress has begun the process of reauthorizing the *Prescription Drug User Fee Act (PDUFA)* reauthorization, and the *Medical Device Use Fee (MDUFA) Act, which expire in September 2012, and to* authorize the new *Generic Drug User Fee Act (GDUFA).*The House Committee on Energy and Commerce has scheduled a series of hearings over the next few weeks to discuss user fee issues. On February 1, 2012, a hearing was convened to discuss the reauthorizations of the PDUFA, the Best Pharmaceuticals for Children Act (BPCA), and the Pediatric Research Equity Act (PREA). All expire on September 30, 2012. PDUFA was first authorized by Congress in 1992 in order to expedite human drug applications through the FDA drug approval processes. This year's agreement increases the communication between FDA and drug sponsors with a new 60 day validation period prior to clock officially starting at the FDA. BPCA allows the FDA to extend a six-month period of market exclusivity to a manufacturer in return for specific studies on pediatric use. PREA requires a manufacturer to submit studies on the safety and effectiveness of a drug when used in children. FDA Director Margaret

Hamburg, MD, testified at the hearing. Other witness included representatives of the biotech industry, and patient groups. Upcoming hearing topics include generics and biosimilars on February 7, 2012, medical devices on February 15, 2012, and general user fee issues on March 7, 2012, Additional hearings may be scheduled in March 2012 and committee action on FDA user fee legislation is expected in April 2012. The separate user fee bills are likely to be combined into a larger bill and other FDA concerns, such as an improved conflict of interest vetting process, will be considered for inclusion. AANS/CNS Washington Office staff members are participating in a workgroup of specialty society staff to review and support provision of interest to specialty medicine.

More information on the FDA agreement with device manufacturers is available at:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm289828.htm

More information on the hearings is available at:
http://energycommerce.house.gov/hearings/hearingdetail.aspx?NewsID=9194

510(k) Process

On January 31, 2012, Rep. Edward Markey (D-MA) introduced H.R. 3847, the Safety of Untested and New Devices Act of 2012, also referred to as "SOUND Devices Act of 2012." The bill attempts to limit the number of devices that may be available for use as substantial equivalent predicates used for 510(k) applications. The key provisions include:

- Submitters of 510(k) notifications would be required to include information about the history of corrections and removals of the predicate device and the predicates of that predicate;
- FDA may reject a claim of substantial equivalence if the predicate device or its predicates were corrected or removed, or if FDA is in the process of taking regulatory action against the predicate or its predicates, due to an "intrinsic flaw in technology or design that adversely affects safety";
- FDA may reject a claim of substantial equivalence if the predicate was corrected or removed and the manufacturer failed to report such correction or removal; and
- When a device is corrected or removed because of an intrinsic flaw in technology or design that adverse affects safety, FDA may order manufacturers of devices "in the same lineage" to submit a report stating whether their device shares the same intrinsic flaw, and if not, why not.

Supporters of the appropriate use of the 510(k) pathway are concerned that the bill would make access to the 510(k) more difficult. The FDA currently has sufficient statutory authority to ensure the quality of the devices cleared through the 510(k) process, and it frequently exercises it. More information is available at:
http://markey.house.gov/press-release/markey-waxman-schakowsky-delauro-introduce-legislation-close-loophole-flawed-medical

Food and Drug Administration Activities

Off-Label Guidance Document

In December 2011, FDA issued a draft guidance document entitled *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*. The draft provides recommendations for industry response to unsolicited requests for off-label information, issues surrounding the scientific exchange of information prior to approval, and the agencies views on clinical material shared via social media. Comments are due by March 29, 2012. AANS and CNS Washington Office staff are working with the Alliance of Specialty Medicine to determine if we should develop comments. More information is available at: http://1.usa.gov/uDN4Ys

FDA Neurological Devices Panel to Consider Cranial Electrotherapy Stimulator

On February 10, 2012, the FDA Neurological Devices Advisory Committee will met to discuss and make recommendations regarding the possible reclassification of cranial electrotherapy stimulator (CES)

devices. On August 8, 2011, FDA issued a proposed rule which, if made final, would make CES devices Class III requiring premarket approval. CES technology has been on the market for 30 years and is approved for over-the-counter sales in Europe, Canada and China. The meeting notice is available on the web at: http://www.gpo.gov/fdsys/pkg/FR-2011-11-16/pdf/2011-29528.pdf

FDA Sponsored Workshop on "Patient-Centeredness"

On February 5, 2012, ECRI Institute, a consulting firm specializing in patient safety, quality improvement, risk management, medical devices, healthcare technology, procurement, and health policy, posted a video of the public conference it hosted with the FDA on November 29 and 30,2011, titled, **"**Patient-Centeredness in Policy and Practice: A conference on evidence, programs, and implications". The video may be seen at www.ecri.org/2011conf. Speakers included representatives of the Washington State Health Care Authority, American College of Surgeons, American College of Physicians, industry, and academic medical centers. The ECRI institute has produced numerous technology assessments for groups such as the Agency for Healthcare Research and Quality, and the Washington State Technology Assessment Committee. Zachery Litvack, MD, and AANS/CNS Washington Office Staff attended the meeting. More information is available at: https://www.ecri.org/Press/Pages/ECRI-Institute-and-FDA-Announce-Top-Speakers-for-Free-Patient-Centeredness-Conference.aspx

FDA Workshop on Evidence Development

The Food and Drug Administration (FDA) held a public workshop on December 2, 2011, entitled, "Bridging the IDEAL and TPLC Approaches for Evidence Development for Surgical Medical Devices and Procedures". The purpose of the public workshop was to provide a forum for discussion among FDA, governmental agencies, academia, physicians and various stakeholders to further refine and advance the IDEAL initiative (Idea Development Exploration, Assessment and Long-Term Study) and TPLC (Total Product Life Cycle) frameworks related to evidence generation and evaluation for surgical devices and procedures. More information is available on the web at: http://www.gpo.gov/fdsys/pkg/FR-2011-11-07/html/2011-28722.htm

FDA Meetings for MDUFA Reauthorization

Over the last year, FDA has hosted 12 meetings with physician specialty society, patient, and consumer group stakeholders during the Medical Device User Fee Act (MDUFA) negotiation process. The next meeting is scheduled for February 28, 2012. .Presumably this will be the final meeting of FDA with the stakeholders and will include a review of the final agreement between FDA and industry that was forwarded to Congress on February 1, 2012. More information on the MDUFA negotiation process is available on the web at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm

UDI Regulations at OMB since July

FDA sent a draft proposed rule for the adoption, implementation, and use of unique device identifiers (UDIs) to the Office of Management and Budget (OMB) in July 2012 but the proposed regulation still has not been published. The proposed rule would require device-makers to label their products with a bar-code-like unique identifier that would make it easier to track the devices and would expedite recalls, if necessary.OMB will not comment on the reason for the delay. More information is available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

FDA Gathering Data on Pediatric Devices

On January 25, 2012, the FDA announced that it would reopen until March 5, 2012, an opportunity to comment on factors affecting the use of scientific research data to support pediatric medical device

efficacy claims. The FDA held a public workshop on December 5, 2011, entitled: "Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue." The purpose of the workshop was to gather information on the use of scientific research data, including published scientific literature, to extrapolate effectiveness claims from adults to children and between pediatric subpopulations in order to support and establish pediatric indications for medical devices. Topics discussed at the meeting included the ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling. More information is available at: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm278053.htm

FDA Guidance Document on Sex Differences in Medical Device Clinical Studies

On December 19, 2011, the FDA Center for Devices and Radiological Health's (CDRH) released a guidance document to help industry understand agency expectations regarding sex-specific patient enrollment, data analysis, and reporting of study information. The intent is to improve the quality and consistency of available data regarding the performance of medical devices in both sexes by ensuring appropriate representation by sex in clinical studies of devices, and that data from such studies is appropriately analyzed for sex differences. The specific objectives of this guidance are: 1) to provide recommendations for study design and conduct to encourage enrollment of women in proportions that are representative of the demographics of disease distribution; 2) to outline recommended statistical analyses of study data for sex differences, and to identify sex-specific questions for further study; 3) to encourage the consideration of sex and associated covariates (e.g., body size, plaque morphology, etc.) during the study design stage; and 4) to specify CDRH's expectations for reporting sex-specific information in summaries and labeling for approved devices.

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM283707.pdf?source=govdelivery

Other Drug and Device Activity

AdvaMed Conference Call on MDUFA

On February 8, 2012, the Advance Medical Technology Association (AdvaMed), a trade association for medical device manufactures, has scheduled a conference call to discuss the agreement reached between industry and the FDA on user fees for medical devices. AANS/CNS Washington Office staff will participate in the call.

American Society for Testing and Materials

The American Society for Testing and Materials (ASTM) F04 Committee on Medical and Surgical Materials and Devices has created a subcommittee to review testing standards for intervertebral body fusion devices with integrated fixation components. Jean Coumans, MD has been appointed by the AANS/CNS Spine Section to follow ASTM F04 issues and attended a meeting of the F04 Committee in November. More information on the new standard being developed is available at: http://www.astmnewsroom.org/default.aspx?pageid=2637' General information on the ASTM F04 Committee is available at http://www.astm.org/COMMIT/COMMITTEE/F04.htm

GAO Report on Pediatric Medical Devices

The Government Accountability Office (GAO) released a report on December 20, 2012 entitled *Provisions Support Development, but Better Data Needed for Required Reporting* (GAO-12-225). The report found that there are persistent barriers to the creation of pediatric medical devices, but economic incentives for manufacturers give some hope that there could be more approved pediatric devices in the future. Given the unique characteristics of the pediatric population, and because the market for pediatric

devices is smaller than the market for adult devices, GAO said there are limited economic incentives for manufacturers to develop pediatric medical devices. GAO noted that according to the FDA, development of pediatric devices lags years behind development of devices for adults. To remedy the lag, GAO said the FDA Amendments Act of 2007 (FDAAA) provided incentives to develop devices for children, particularly devices that receive FDA's humanitarian device exemption (HDE), a process for devices that treat or diagnose rare diseases or conditions. In general, manufacturers of devices approved through the HDE process are allowed to recover certain development and production costs but may not make a profit on their device. FDAAA removed that barrier for pediatric devices. More information and a copy of the report are available at: *http://www.gao.gov/products/GAO-12-225*

CRS Report on Riegel vs. Medtronic

The Congressional Research Service published a report **[see ATTACHED]** on January 13, 2012 regarding *Riegel v. Medtronic, Inc.*, in which the United States Supreme Court held in an 8 to 1 decision that if the FDA grants premarket approval (PMA) to a medical device, the device manufacturer is immune from certain suits under state tort law, due to an express preemption provision in the Medical Device Amendments of 1976 (MDA). This holding establishes that FDA PMA preempts claims such as strict liability, breach of implied warranty, and negligence in design, testing, manufacturing, labeling, distribution, sale, inspection, or marketing of the device to the extent that such state law claims are "different from, or in addition to" federal PMA requirements. However, the Supreme Court held that the MDA's express preemption provision did not prohibit state "claims premised on a violation of FDA regulation." The Court stated that such claims "'parallel,' rather than add to, federal requirements." Post-*Riegel*, the lower courts have come to differing conclusions when determining whether particular state law claims, such as manufacturing defect claims, "parallel" federal requirements, and thus are not preempted, or rather are state requirements "different from, or in addition to" federal requirements, and thus are preempted under *Riegel*.

The Supreme Court's decision has been a cause for concern for some Members of Congress who disagree with the ruling, as well as trial lawyers and patients. However, advocates of more limited tort liability, including the previous Administration, agree with the ruling. The decision has broad implications for consumers of Class III medical devices, who are prevented from suing device manufacturers on most state common law claims, as well as manufacturers, who are shielded from many suits if their device receives FDA PMA. In the 111th Congress, bills were introduced—H.R. 1346, H.R. 4816, and S. 540—that would have overturned the Court's decision in *Riegel* by modifying the statute at issue. As of the date of this report, similar legislation has not been introduced in the 112th Congress.

CRS Report on Medical Device Regulation

On December 28, 2011, CRS issued a report on Medical Device Regulation that provides a good overview of the process for reference. **[see ATTACHED]**

IRS Publishes Medical Device Industry Tax Regulations

On February 3, 2012, the Internal Revenue Service published proposed regulations providing guidance on the 2.3 percent excise tax imposed on the sale of certain medical devices, enacted as part of the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act. The proposed regulations affect manufacturers, importers, and producers of taxable medical devices and takes effect in 2013. The document also provides a notice of a May 16, 2012 public hearing on the proposed regulations. A number of members of Congress, including Sen. Orrin Hatch (R-UT) and Congressman Erik Paulsen (R-MN) who have introduced legislation to repeal the tax and issued press statements criticizing the Administration for pushing ahead with plans to implement the tax. A copy of the proposed rule is available at: http://www.ofr.gov/OFRUpload/OFRData/2012-02493_PI.pdf Rep. Paulsen's press release is available at: http://www.paulsen.house.gov/press-releases/paulsen-disappointed-as-obama-administration-moves-to-implement-jobcrushing-medical-innovation-tax/

Riegel v. Medtronic, Inc.: Federal Preemption of State Tort Law Regarding Medical Devices with FDA Premarket Approval

Vanessa K. Burrows
Legislative Attorney

January 13, 2012

Congressional Research Service
7-5700
www.crs.gov
R40534

CRS Report for Congress
Prepared for Members and Committees of Congress

Summary

In *Riegel v. Medtronic, Inc.*, the United States Supreme Court held in an 8 to 1 decision that if the Food and Drug Administration (FDA) grants premarket approval (PMA) to a medical device, the device manufacturer is immune from certain suits under state tort law, due to an express preemption provision in the Medical Device Amendments of 1976 (MDA). This holding establishes that FDA PMA preempts claims such as strict liability, breach of implied warranty, and negligence in design, testing, manufacturing, labeling, distribution, sale, inspection, or marketing of the device to the extent that such state law claims are "different from, or in addition to" federal PMA requirements. However, the Supreme Court held that the MDA's express preemption provision did not prohibit state "claims premised on a violation of FDA regulation." The Court stated that such claims "'parallel,' rather than add to, federal requirements." Post-*Riegel*, the lower courts have come to differing conclusions when determining whether particular state law claims, such as manufacturing defect claims, "parallel" federal requirements, and thus are not preempted, or rather are state requirements "different from, or in addition to" federal requirements, and thus are preempted under *Riegel*.

The Supreme Court's decision has been a cause for concern for some Members of Congress who disagree with the ruling, as well as trial lawyers and patients. However, advocates of more limited tort liability, including the previous Administration, agree with the ruling. The decision has broad implications for consumers of Class III medical devices, who are prevented from suing device manufacturers on most state common law claims, as well as manufacturers, who are shielded from many suits if their device receives FDA PMA. In the 111th Congress, bills were introduced—H.R. 1346, H.R. 4816, and S. 540—that would have overturned the Court's decision in *Riegel* by modifying the statute at issue. As of the date of this report, similar legislation has not been introduced in the 112th Congress.

This report will provide a brief overview of federal premarket regulation of medical devices. The report then provides an overview of federal preemption of state law, as well as arguments for and against federal preemption of state law tort claims with respect to medical devices. The report explains the Supreme Court's decision in *Riegel* and examines the concurring and dissenting opinions. Finally, the report analyzes the legal, procedural, policy, and legislative implications for Congress, consumers, and medical device manufacturers.

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In order to elucidate the Supreme Court's decision in *Riegel v. Medtronic, Inc.*,[1] this report begins by providing background on the Food and Drug Administration's (FDA's) premarket regulation of medical devices and an overview of federal preemption of state law. The report discusses arguments for and against federal preemption of state law tort claims with respect to medical devices. Next, the report examines the FDA's shifting position on federal preemption in medical device cases. The report then explains the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, as well as the concurring and dissenting opinions. Finally, the report analyzes the implications of the Court's decision in *Riegel* for Congress, consumers, medical device manufacturers, and preemption jurisprudence.

This report focuses on Class III medical devices because it is federal preemption of state law requirements that are "different from, or in addition to" federal requirements for Class III devices with premarket approval (PMA) that was at issue in *Riegel*.[2]

An Overview of FDA Premarket Notification and Premarket Approval (PMA) of Medical Devices

The Federal Food, Drug, and Cosmetic Act (FFDCA)[3] sets forth a detailed set of statutory requirements designed to ensure that medical devices are safe and effective. As a result, medical devices must meet certain minimum requirements before they may be marketed in the United States. For example, the device cannot be adulterated or misbranded, and there are registration, good manufacturing practices, and labeling requirements.[4] There are also more specific requirements that a device manufacturer must follow, which are determined by the level of risk that the device poses to patients from its use or misuse.[5]

Medical devices are classified according to risk—Class I (low risk), Class II (moderate risk), and Class III (high risk)—and there are certain requirements based on that risk.[6] Class III devices, which are those "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or those that "present[] a potential unreasonable risk of illness or injury," are generally subject to premarket approval (PMA).[7] Examples of Class III devices include replacement heart valves, silicone gel-filled breast implants, and pacemaker pulse generators.[8]

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[1] 552 U.S. 312 (2008).

[2] 21 U.S.C. § 360k(a). Preemption of tort suits related to drugs that have received FDA approval, which was at issue in *Wyeth v. Levine*, and federal preemption of state tort claims related to generic prescription drug labeling, which was at issue in *Pliva, Inc. v. Mensing*, will not be addressed in this report.

[3] 21 U.S.C. §§ 301 *et seq*.

[4] 21 U.S.C. §§ 351-52, 360; 21 C.F.R. Parts 801, 809, and 820.

[5] The term "manufacturer" here includes any person, organization, or sponsor that submits a PMA application to THE FDA for a medical device.

[6] 21 U.S.C. § 360c.

[7] 21 U.S.C. § 360c(a)(1)(C)(ii).

[8] 21 C.F.R. § 870.3925 (replacement heart valve); 21 C.F.R. § 878.3540 (silicone gel-filled breast prosthesis); 21 C.F.R. §§ 870.3600, 870.3610 (respectively, external pacemaker pulse generator and implantable pacemaker pulse generator). *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008)(citing replacement heart valves and pacemaker pulse generators).

All new devices are automatically designated as Class III, and therefore must receive PMA, unless the device meets one of three exceptions: (1) the "grandfather" provision for devices on the market prior to the passage of the Medical Device Amendments of 1976 (MDA),[9] (2) a device on the market after the passage of the MDA that has been classified as Class I or Class II or reclassified as Class I or Class II by the FDA after the manufacturer files a petition for reclassification,[10] or (3) the device is "substantially equivalent" to either a grandfathered device or a Class I or Class II device.[11] A device is "substantially equivalent" if the FDA makes such a determination based on a comparison of the new device with a predicate device.[12] A predicate device could have been marketed either before or after 1976.[13] The device seeking the "substantially equivalent" determination must either have (1) the same intended use[14] and the same technological characteristics as the predicate device, or (2) the same intended use, different technological characteristics, and information and data that demonstrate safety and effectiveness, and cannot "raise different questions of safety and effectiveness than the predicate device."[15] The manufacturer decides which predicate device to use for the comparison with the new device. However, the FDA has discretion in determining whether the comparison is appropriate.

Premarket Notification (§ 510(k) Submissions)

Premarket notification is known as a § 510(k) submission, after the section of the FFDCA that requires it. Class III devices generally require a premarket notification as well as PMA. However, some Class III devices may be marketed only with a § 510(k) submission—if the device was introduced after the passage of the MDA in 1976 and is substantially equivalent to a pre-1976 device, but there is no regulation requiring PMA.[16] The majority of new Class III medical devices reach the marketplace after a § 510k submission, as opposed to the receipt of FDA PMA.[17]

Premarket notification applies to new devices that are not substantially equivalent to pre-1976 devices, devices introduced after passage of the MDA in 1976 that have been reclassified as Class I or Class II, and devices that may have been or currently are on the market, but that have been significantly modified.[18] At least 90 days before a manufacturer may market one of these new devices, the manufacturer must submit a notification to the FDA.[19] After the FDA reviews a premarket notification under § 510(k), the agency may find that the device either is or is not substantially equivalent to a predicate device, request more information, withhold a decision

[9] 21 U.S.C. § 360c(f)(1). Approximately 1,700 different generic types of medical devices that existed on the market in 1976 were "grandfathered" in under the MDA and classified in the Code of Federal Regulations.

[10] 21 U.S.C. § 360c(f)(1)(A)(i)(II); 21 U.S.C. § 360c(f)(1)(B); 21 C.F.R. § 860.3(c)(3).

[11] 21 U.S.C. § 360c(f)(1)A)(ii).

[12] 21 U.S.C. § 360c(i)(1)(A).

[13] 21 U.S.C. § 360c(f)(1)(A).

[14] Intended use and indications for use provide the basis for risk classification and, therefore, the types of studies that are required to support approval or clearance of the device, and the stringency of the regulations with which the manufacturer will have to comply.

[15] 21 U.S.C. § 360c(i)(1)(A).

[16] *See* 21 U.S.C. §§ 360c(f)(1), 360e(b), (i).

[17] Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008).

[18] 21 C.F.R. § 807.81(a). Manufacturers may use a § 510(k) when seeking a new indication (e.g., a new population, such as pediatric use, or a new disease or condition), or when changing the design or technical characteristics.

[19] 21 U.S.C. § 360(k); FFDCA § 510(k). The submission must contain the information required in 21 C.F.R. § 807, Subpart E.

pending the submission of certain information, or advise the submitter that the device does not require premarket notification.[20]

Premarket Approval (PMA)

As noted above, a PMA application is required for most Class III devices, with three exceptions.[21] In the PMA process, the FDA determines if these devices have a "reasonable assurance of ... safety and effectiveness."[22] A PMA application must include, among other facts, information regarding proposed labeling, reports of information "concerning investigations which have been made to show whether or not such device is safe and effective," a description of the manufacturing and processing methods, samples of the device and its components, and information regarding the components, ingredients, and operating principles of the device.[23] A PMA application will be denied approval if "there is a lack of a showing of reasonable assurance that such device is safe [and effective] under the conditions of use" in the proposed labeling; if the methods of manufacturing, processing, packing, or installing the device do not conform to good manufacturing practices; if the proposed labeling is false or misleading; or if the device does not meet performance standards.[24] The FDA cannot disclose the existence of a PMA application file before issuing an approval order to the applicant "unless it previously has been publicly disclosed or acknowledged."[25]

PMA Supplements

Once a device has been approved through the PMA process, the manufacturer can market the device only for its intended use. For example, a device, such as a stent, approved to treat coronary artery disease may not be marketed for treatment of blocked biliary ducts unless the manufacturer files a PMA supplement for FDA review and approval.[26] The FDA must approve the PMA supplement before the manufacturer may make a "change affecting the safety or effectiveness of the device for which the applicant has an approved PMA," such as changes to the labeling, packaging, sterilization procedures, and new indications for use of the device (as in the stent example).[27] However, in certain cases, a change to a device with PMA "that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt ... of a written FDA order approving the PMA supplement."[28]

[20] 21 C.F.R. § 807.100(a).

[21] 21 U.S.C. § 360e(a). The three exceptions to the PMA requirement are: (1) devices on the market prior to the enactment of the Medical Device Amendments of 1976, 21 U.S.C. §§ 360e, 360c(f); (2) devices for which there is an investigational device exemption, 21 U.S.C § 360j(g); and (3) devices that the FDA has determined are substantially equivalent to those already on the market under the § 510(k) premarket notification process, 21 U.S.C. § 360e(b)(1)(B).

[22] 21 U.S.C. § 360c(a)(C).

[23] 21 U.S.C. § 360e(c)(1). In contrast to a § 510(k) submission, PMAs generally require some clinical data.

[24] 21 U.S.C. § 360e(d)(2); 21 C.F.R. Part 814.

[25] 21 C.F.R. § 814.9(b); *see also* 21 C.F.R. §§ 814.9(e)-(f). "Upon issuance of an order approving, or an order denying approval of any PMA, FDA will make available to the public the fact of the existence of the PMA." 21 C.F.R. § 814.9(e).

[26] 21 C.F.R. § 814.39(a).

[27] 21 C.F.R. § 814.39(a); 21 U.S.C. § 360e(d)(6).

[28] 21 C.F.R. § 814.39(d)(1).

Preemption

This section will first provide an overview of federal preemption of state law. It will then discuss arguments for and against preemption of state law tort claims with respect to medical devices. Finally, this section will discuss the change in the FDA's position on preemption in medical device cases.

Federal Preemption of State Law

The preemption doctrine is derived from the Supremacy Clause of the U.S. Constitution, which establishes that the laws of the United States "shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding."[29] In applying this constitutional mandate, courts have recognized both express and implied forms of preemption, which are "compelled whether Congress' command is explicitly stated in the statute's language, or implicitly contained in its structure and purpose."[30] Both types of preemption may apply to state legislation, regulations, and common law. As the Supreme Court held in *Gade v. National Solid Wastes Management Association*, "the question whether a certain state action is pre-empted by a federal law is one of congressional intent. The purpose of Congress is the ultimate touchstone. To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute."[31]

In the *express* preemption context, a federal statute will be deemed to supplant existing state law to the extent that it contains an explicit provision to that effect, the scope of which is determined by interpreting the language of the provision and analyzing the legislative history as necessary.[32] Where express preemption provisions are not present, federal law may preempt state law implicitly. There are several different ways to conceptualize the doctrine of *implied* preemption, but it is often subdivided into three general categories for purposes of analysis: (1) federal occupation of the entire field of regulation; (2) actual conflict between federal and state requirements; and (3) state requirements that frustrate congressional purpose.[33]

Courts, however, often encounter difficulty when federal law is silent as to the preemptive effect. The Supreme Court traditionally begins its analysis in this context with a presumption against preemption, an "assumption that the historic police powers of the States were not to be superseded by [a federal law] unless that was the clear and manifest purpose of Congress."[34] Several decisions by the Court have strengthened this presumption, including *Maryland v. Louisiana*, which stated that "[c]onsideration under the Supremacy clause starts with the basic

[29] U.S. CONST. art. VI, cl. 2.

[30] Gade v. National Solid Wastes Management Association, 505 U.S. 88, 97 (1992) (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

[31] *Id.* at 96 (internal quotation marks and case citations omitted).

[32] *Jones*, 430 U.S. at 525.

[33] Sprietsma v. Mercury Marine, 537 U.S. 51, 64 (2002); *see also* Hines v. Davidowitz, 312 U.S. 52, 61, 77 (1941) (regarding field and frustration of purpose preemption); Florida Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963) (regarding conflict preemption).

[34] *See* Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 605 (1991); *see also* Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

assumption that Congress did not intend to displace state law,"[35] and *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, which held that "[p]reemption of state law by federal statute or regulation is not favored 'in the absence of persuasive reasons either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably ordained.'"[36] Additionally, in the Supreme Court case *Medtronic, Inc. v. Lohr*, which also addressed preemption of state tort claims under the MDA, the plurality opinion noted:

> Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are "primarily, and historically, ... matter[s] of local concern," *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985), the "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U.S. 724, 756 (1985) (internal quotation marks omitted).[37]

These standards, however, are highly case specific in their application. Indeed, the Supreme Court itself has noted that "none of these expressions provide an infallible constitutional test or an exclusive constitutional yardstick. In the final analysis, there can be no crystal clear distinctly marked formula."[38] Thus, cases involving federal preemption of state law often hinge on the particular factual circumstances of a given case.

Arguments for Federal Preemption of State Law Tort Claims with Respect to Devices

There are policy arguments for and against the merits of preemption in the medical device context. Arguments for federal preemption of common law in the medical device context focus on (1) uniform national standards, (2) the rigor of the PMA process, (3) the FDA's expertise in this field, and (4) the potential for delay in the development of new products. Businesses tend to favor preemption, as regulated industries "generally prefer uniform, national regulation over varying state regulation."[39]

Those in favor of preemption, including the Pharmaceutical Research and Manufacturers of America (PhRMA) and trade groups for medical device makers such as the Advanced Medical Technology Association (AdvaMed), equate jury verdicts under state common law with the imposition of a state law "requirement" in addition to "requirements" that are imposed for devices under the FFDCA and FDA regulations.[40] For example, medical device manufacturers have

[35] 451 U.S. 725, 746 (1981).

[36] 450 U.S. 311, 317 (1981) (quoting Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142 (1963)).

[37] 518 U.S. 470, 475 (1996).

[38] *Hines,* 312 U.S. at 67.

[39] Marcia Coyle, *High Stakes for Regulated Industry in Supreme Court Pre-emption Cases*, The National Law Journal, Nov. 30, 2007. One court stated that "[t]he legislative history indicates that [national uniformity] was the reason the preemption provision was included within the MDA. H.R. Rep. No. 853, 45 (1976) ("If a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.")." Brooks v. Howmedica, 273 F.3d 785, 797 (8th Cir. 2001).

[40] *See* Samuel Loewenberg, *Lawmakers Try to Remove Tort Shield*, Politico, June 18, 2008; Press Release, PhRMA, PhRMA Statement on Federal Preemption (June 11, 2008), http://www.phrma.org/news_room/press_releases/phrma_statement_on_federal_preemption. The U.S. Chamber of Commerce argued that the MDA's "express preemption provision is deliberately broad." Coyle, *supra* note 39.

argued that in light of the rigor of the FDA's PMA process[41] and its resulting "device-specific design, manufacturing, and labeling requirements," separate jury verdicts would also produce "requirements" as a practical matter with regard to a device's design, manufacture, or label.[42] One court of appeals case explained the effect of a jury verdict this way:

> The effect of a jury finding of negligent failure to warn would be that state law would require [the manufacturer] to change the label and package insert for [the medical device], but [the manufacturer] may not unilaterally make such changes under federal law. A device may not be labeled in a manner inconsistent with any conditions specified in its PMA. 21 C.F.R. § 814.80 (2000). A manufacturer must submit a Supplemental PMA for any proposed labeling changes that affect the safety of the device. *Id.* at § 814.39(a).[43]

Others in favor of preemption, such as the George W. Bush Administration, similarly have pointed to the FDA as an agency composed of expert scientists vested with authority to undertake matters such as PMA, which should not be overruled by potentially inconsistent state juries. They argue that juries lack the FDA's expertise to engage in a balancing of the benefits and risks that products may pose.[44] Finally, preemption advocates argue that to decide differently may delay or discourage development and marketing of products with beneficial or even life-saving potential, and that recalls of medical devices are "rare."[45] They also respond to the argument that preemption does not give the manufacturer the incentive to update and improve its devices by saying that market pressures will force companies to change their products.[46]

Arguments Against Federal Preemption of State Law Tort Claims with Respect to Devices

In contrast, arguments against federal preemption of common law in the medical device field focus on (1) congressional intent and legislative history, (2) protections for consumers, who may otherwise be left without a remedy, (3) the change in the FDA's view with regard to preemption, as well as the general presumption against preemption, (4) viewing FDA approval as a preliminary step—a "floor" rather than a "ceiling"—that does not hold manufacturers accountable for safety concerns, and (5) questioning the agency's capabilities in terms of resources and its reliance on industry.

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[41] "The FDA scrutiny process takes years and millions of dollars to prove a device's safety and efficacy. ... companies emerge only to be sued when something goes wrong, as is prone to happen in patients with serious medical conditions and with devices more technologically advanced than ever." Editorial, *Medical Double Jeopardy*, Wall Street Journal, Mar. 1, 2008, at A8.

[42] Coyle, *supra* note 39 (discussing the arguments of Medtronic's attorneys in *Riegel*).

[43] Brooks v. Howmedica, 273 F.3d 785, 796 (8th Cir. 2001).

[44] Shannon P. Duffy, *Pre-emption Issue Weighed in Label Cases*, The Legal Intelligencer, Dec. 14, 2007; Linda Greenhouse, *Supreme Court Hears Medical Device Case*, N.Y. Times, Dec. 5, 2007; Anna Edney, *High Court Case Will Define Parameters of 1976 Medical Law*, Congress Daily AM; Sam Baker, *Supreme Court Hears Arguments in FDA Preemption Case; Breyer Seen as Swing Vote*, FDA Week. At oral argument in *Riegel*, Justice Kennedy "noted that the FDA is 'specifically charged with weighing the risks against the probable benefits,' and in a state product liability case, 'the jury is doing the same thing that the FDA did.'" Laurel Newby, *Supreme Court Argument Report: Justices Mull Pre-emption of Product Liability Claims*, Law.com, Dec. 5, 2007.

[45] Greenhouse, *supra* note 44; Edney, *supra* note 44; Newby, *supra* note 44; Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), Amicus Brief for AdvaMed and DRI, 2007 U.S. S. Ct. Briefs LEXIS 1290, at *1.

[46] Baker, *supra* note 44.

With regard to congressional intent, some commentators have noted that "Congress did not directly address tort suits in the MDA, despite decades of lawsuits against drug manufacturers."[47] Opponents of federal preemption of state common law claims in the device area, such as Senator Kennedy and Congressman Waxman, have argued that Congress's silence on the issue evidences "its intent not to preempt the suits,"[48] or alternately, that the discussions in the legislative history do not provide evidence of such intent.[49] In *Riegel*, discussed below, the plaintiffs' attorney also questioned whether Congress would "have really intended to protect the manufacturer from liability," since the passage of the MDA occurred in the wake of the Dalkon Shield cases,[50] in which an intrauterine device "was linked to serious infections and several deaths, not to mention a large number of pregnancies."[51]

Some who are against preemption view tort law as an "important and necessary adjunct to the regulatory process"[52] and cite the FDA's view prior to 2004 that federal law did not preempt product liability lawsuits.[53] While proponents of preemption see it as a way to protect orderly business functions, others assert that "industry has been pushing to expand federal pre-emption for the past 25 years as a wholesale, get-out-of-jail-free card."[54] The Riegels' counsel and others have argued that FDA PMA should be seen as "a preliminary judgment of safety and effectiveness that did not relieve a manufacturer of an obligation to make a device better and safer."[55]

Moreover, as the Justices explored at oral argument in *Riegel*, preemption could shield manufacturers who discover a risk or problem with their FDA-approved device, if the FDA has not yet learned of the problem or has not taken action as a result of the risk.[56] It could be argued that the FDA is dependent on manufacturers to provide information regarding devices, that "[t]here is no opportunity for public comment or for any public challenge to the information presented to the FDA by the device manufacturer" in the PMA application, and to allow the common law tort claims to go forward may reveal information in the discovery process that manufacturers withheld from the FDA in the PMA process.[57] This view sees the state tort law

[47] Baker, *supra* note 44.

[48] *Id.*

[49] Brief for Amici Curiae Senator Kennedy and Congressman Waxman, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *3.

[50] Newby, *supra* note 44.

[51] Riegel v. Medtronic, 552 U.S. 312, 315 (2008).

[52] Duffy, *supra* note 44.

[53] Greenhouse, *supra* note 44. Deputy solicitor general Edwin S. Kneedler argued that the FDA's policy change on preemption "recognized that there would be a serious undermining of F.D.A.'s approval authority and its balancing of the risks and benefits if a state jury could reweigh those." *Id.* At oral argument in *Riegel*, the government asserted that it "filed a brief in - - late 1997 taking a position that PMA approval did *not* ... have preemptive effect." (emphasis added). Transcript of Oral Argument at 45, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf. According to the government, at approximately the same time the agency issued a proposed rule—that it withdrew seven months later—and that proposed rule asserted that PMA approval did *not* have preemptive effect. *Id.*

[54] Coyle, *supra* note 39.

[55] Greenhouse, *supra* note 44; Baker, *supra* note 44.

[56] Greenhouse, *supra* note 44; *see infra* notes 146-48.

[57] Kennedy v. Collagen Corp., 67 F.3d 1453, 1456 (9th Cir. 1995); Baker, *supra* note 44; s*ee also* Editorial, *Our View on Pharmaceutical Safety: If a drug has FDA's OK, should you be able to sue?*, USA Today, Apr. 25, 2008 (noting that Merck, which made Vioxx, "apparently downplayed evidence that the medicine tripled the death risk in Alzheimer's-prone patients").

system as a backstop, as safety concerns may "have been uncovered not by the agency but during the course of litigation."[58] Concerns have been raised that companies may also not "respond to safety concerns that arise after a product is on the market," if federal law preempts state tort claims, or even attempt to manufacture new devices that are safer or better because suits related to marketing previously approved devices would be preempted.[59] Those who view the agency as overburdened may also similarly view the agency's PMA process as inadequate to protect patients.[60]

The FDA's Position on Preemption in Medical Device Cases

Over the years, the FDA's position on preemption of state tort law claims in medical device cases has shifted.[61] This section will discuss the express preemption provision, as well as the FDA's positions since the provision was first enacted in 1976.

The FFDCA contains an express preemption provision with respect to medical devices. This provision was included as part of the MDA, which was enacted in 1976. The statute, 21 U.S.C. § 360k(a), which was at issue in *Riegel*, provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from or in addition to, any requirement applicable under [federal law] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [relevant federal law].[62]

However, the agency may exempt state requirements that are "more stringent" and state requirements "required by compelling local conditions" if "compliance with the requirement would not cause the device to be in violation of any applicable requirement under" the FFDCA.[63]

The FDA subsequently issued regulations interpreting this preemption provision in 1978, which were amended after the Supreme Court issued its decision in *Medtronic, Inc. v. Lohr*.[64] In that

[58] Lawrence O. Gostin, *Reply*, J. AM. MED. ASS'N 1882 (Oct 23, 2008).

[59] Baker, *supra* note 44; *see infra* notes 146-48.

[60] *See* Gardiner Harris, *Justices Add Legal Complications to Debate on F.D.A.'s Competence*, N.Y. Times, Feb. 21, 2008, at C4; Karl Thiel, *Supreme Court Actions Add Pressure to Beleaguered FDA*, Bioworld Today, Vol. 19, Issue 42, Mar. 3, 2008. Congress has held multiple hearings on the FDA's lack of resources as compared to its obligations. *See, e.g.*, *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?*: *Hearing Before the H. Comm. on Oversight and Gov't Reform*, 110th Cong., May 14, 2008.

[61] Former FDA Commissioner Donald Kennedy has argued that the "notion of preemption has taken on an entirely new guise, also involving the FDA, but in a far more troubling way than the older use of preemption in the regulatory sense." Donald Kennedy, Editorial, *Misbegotten Preemptions*, 320 SCIENCE 585 (May 2, 2008). He asserts that the FDA used preemption in the late 1970s, when he was commissioner of the agency, in a way that prevented states from establishing their own requirements, such as "net weight requirements for packaged foods" that may "disfavor our-of-state competition," or their "own drug approval agenc[ies]." *Id.*

[62] 21 U.S.C. § 360k(a); FFDCA § 521(a).

[63] 21 U.S.C. § 360k(b).

[64] 43 Fed Reg. 18665 (May 2, 1978); 45 Fed. Reg. 67336 (Oct. 10, 1980); 61 Fed. Reg. 52606, 52654 (Oct. 7, 1996).

case, the Court concluded that state common law negligence actions against manufacturers of devices found by the FDA to be "substantially equivalent" under the § 510(k) process were not preempted. In the agency's post-*Lohr* 1996 final rule amending the regulations, the FDA noted that "the new quality system regulation does not preempt State tort and common law remedies."[65] The regulations presently provide:

> State or local requirements are preempted *only* when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from or in addition to, the specific Food and Drug Administration requirements.
>
> …
>
> Section 521(a) [21 U.S.C. § 360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices ... or to unfair trade practices in which the requirements are not limited to devices....[66]

As indicated by these regulations, the FDA's position, prior to the early 2000s, was of a "long-standing presumption against preemption in implementing section 521" of the FFDCA (21 U.S.C. § 360k).[67] The agency's outlook with regard to the scope of the preemption provision was that it "should be interpreted narrowly, with a presumption against preemption."[68] With regard to whether the preemption provision applied to state tort claims, the "FDA did not have occasion to address the precise issue of whether [21 U.S.C. § 360k] preempts state tort claims before that issue was litigated in private lawsuits."[69] In 1997, the then-Chief Counsel of the FDA argued that "although the agency had not formally expressed its position on the precise issue, it is clear from the views it expressed in many other contexts [such as a 1984 advisory opinion, a response to a 1980 request from California for an exemption from preemption, and a response to "a congressional request for an opinion on the preemptive status of another California statute"] that it did not believe that state tort claims were preempted under" 21 U.S.C. § 360k.[70] She referred to the statute's legislative history, the exemption procedure, and the lack of congressional mention of its intent to preempt state common law claims when noting the agency's "belie[f] that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state."[71]

Meanwhile, in *Lohr*, the agency had argued in an *amicus* brief that "state tort claims generally are not preempted under" 21 U.S.C. § 360k.[72] After the Supreme Court's decision in *Lohr*, the then-Chief Counsel for the FDA, Margaret J. Porter, stated:

> FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device

[65] 61 Fed. Reg. 52601, 52603 (Oct. 7, 1996).

[66] 21 C.F.R. § 808.1(d) (emphasis added).

[67] Margaret J. Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 7 (1997).

[68] *Id.*

[69] *Id.* at 8.

[70] *Id.*

[71] *Id.* at 8-9.

[72] *Id.* at 10.

> may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices. Moreover, FDA's regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress when section 521 [21 U.S.C. § 360k] was enacted.[73]

The FDA's view on preemption in medical device cases appeared to shift in 2004, when the agency filed an appellate brief in *Horn v. Thoratec Corp.*, in which the plaintiff sued the medical device manufacturer alleging negligence, defective design, defective manufacture, and failure to warn.[74] In *Horn*, the FDA submitted an *amicus curiae* letter brief to the court, which the court referenced, in which the agency "unequivocally expressed the opinion that state common law claims such as those made by Horn against a PMA-approved device are preempted."[75]

However, the shift may have occurred earlier. As the court in *Horn* noted, the FDA argued in a 2003 statement of interest in a Tennessee circuit court case that PMA "triggers preemption of a wide array of requirements imposed under state tort law."[76] Others have argued that the agency's support of preemption began even prior to the change of presidential Administrations from Bill Clinton to George W. Bush, although this assertion was not limited to medical device cases.[77] One scholar has characterized preemption "as a fundamentally political issue."[78]

In its 2004 amicus brief in *Horn*, the agency specifically acknowledged that it was disclaiming its previous view that 21 U.S.C. § 360k "does not preempt a state tort law claim concerning an FDA-approved device,"[79] which the agency had articulated in a 1997 *amicus* brief.[80] The agency gave several reasons for its change in position. The FDA previously asserted that its approval of a manufacturer's design did not "convert the features of that design into federal requirements," but now stated that such a "proposition does not adequately account for the highly detailed ... nature of the PMA process."[81] The agency also noted that its past position viewed the PMA process as a

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[73] Brief for Amici Curiae Senator Kennedy and Congressman Waxman, Riegel v. Medtronic, 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *20-*21 (quoting Porter, *supra* note 67, at 11). Justice Ginsburg also quoted portions of the above paragraph in her dissent in *Riegel*, noting that "the FDA's long-held view on the limited preemptive effect of § 360k(a) better comports with the presumption against preemption of state health and safety protections, as well as the purpose and history of the MDA." Riegel v. Medtronic, Inc., 552 U.S. 312, 338 n.8 (2008) (Ginsburg, J. dissenting).

[74] 376 F.3d 163, 165 (3d Cir. 2004).

[75] *Id.* at 171.

[76] *Id.* at 171 n. 13; *see also id.* at 178.

[77] Drug and Device Law, The FDA's Amicus Curiae Briefs on Preemption—Redux, http://druganddevicelaw.blogspot.com/2007_10_01_archive.html.

[78] Samuel Raymond, *Judicial Politics and Medical Device Preemption After* Riegel, 5 NYU J. L. & LIBERTY 745, 752 (2010). *See generally* Jennie Holman Blake, *Presidential Power Grab or Pure State Might? A Modern Debate Over Executive Interpretations on Federalism*, 2000 B.Y.U.L. Rev. 293 (discussing executive orders issued by Presidents Reagan and Clinton on federal preemption of state law).

[79] Brief for Amicus Curiae U.S. Dep't of Justice, Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2000) (No. 02-4597), at 3, 28.

[80] Smiths Industries Medical Systems, Inc. v. Kernats*, cert. denied*, 522 U.S. 1044 (1998).

[81] Brief for Amicus Curiae U.S. Dep't of Justice, Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2000) (No. 02-4597), at 28.

minimum standard, which "should not displace state common law that may provide additional protection to consumers," but said in its 2004 *amicus* brief that PMA "sets a ceiling as well as a floor."[82] Finally, the FDA noted that its position change "reflects in part the decisions applying *Lohr* issued by the federal courts" since the Supreme Court issued that opinion.[83]

The agency's view under the George W. Bush Administration was that state common law tort claims, such as those at issue in *Horn* and *Riegel*, are preempted under 21 U.S.C. § 360k because the FDA granted PMA, which imposes specific federal requirements on the Class III medical device at issue, and the state common law claims "would impose a requirement different from, or in addition to, the requirements imposed by FDA in granting pre-market approval."[84] The agency previously stated that even though it does not issue specific federal regulations for a device, "the agency's approval of this device through the PMA process does impose specific requirements for the product, including requirements for its design, manufacturing, performance, labeling, and use," which are based on the manufacturer's PMA application.[85] Additionally, the agency asserted that five Justices in *Lohr* "concluded that a state common law tort judgment is a 'requirement' under Section 360k(a)."[86] Therefore, under the agency's view of preemption during the Bush Administration, "any finding of liability based upon [a device manufacturer's] failure to satisfy a standard different from those approved by the FDA in the PMA process would necessarily rest upon an implicit requirement that this device be designed, manufactured, or marketed in a way that differs from the way approved by FDA."[87]

Though the *Riegel* decision was issued before the start of the Obama Administration, the President announced his policy on preemption in a 2009 memorandum, which stated that "preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption."[88] The memorandum explicitly addressed the inclusion of preemption statements in regulatory preambles and said such statements should not be included unless the preemption provision is included in the regulation itself. Additionally, such provisions should not be included in the regulation unless they were "justified under legal principles governing preemption," including those in President Clinton's Executive Order 13132 on federalism.[89] That executive order requires agencies to "construe … a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."[90] When addressing preemption in terms of federal requirements in recent regulations, the FDA has cited President Clinton's executive order on federalism as well as the Supreme Court's holding in *Riegel*.[91]

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[82] *Id.* at 29.

[83] *Id.* at 30.

[84] Brief for Amicus Curiae U.S. Dep't of Justice, Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2000) (No. 02-4597), at 1-2, 15.

[85] *Id.* at 15-16.

[86] *Id.* at 19.

[87] *Id.* at 18.

[88] President Obama, Memorandum for the Heads of Executive Departments and Agencies, Preemption (May 20, 2009).

[89] *Id.*

[90] Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999).

[91] *See, e.g.*, FDA, Medical Devices; Ovarian Adnexal Mass Assessment Score Test System; Labeling; Black Box Restrictions, 76 Fed. Reg. 82129, 82131 (Dec. 30, 2011).

The Obama memorandum also called upon agencies to review regulations issued in the previous 10 years that included statements in the preamble or the regulation itself with regard to preemption of state law.[92] A 2008 *Associated Press* article noted that 51 regulations proposed or adopted since 2005 had placed limits on lawsuits and that a combined 41 of those 51 came from the FDA and the National Highway Traffic Safety Administration.[93] In 2011, the FDA issued its preemption review. The FDA concluded that its position on preemption that had been articulated in the preamble to a rule on supplemental applications for labeling changes for prescription drugs, biologics, and devices—a position also referenced in rules on nonprescription drugs and food labeling—could not "be justified under legal principles governing preemption."[94] These legal principles included the Supreme Court's decision in *Wyeth v. Levine*, which explicitly addressed the FDA's preemption position in that labeling rule.[95]

Riegel v. Medtronic, Inc.

This section will discuss the Supreme Court's 2008 decision in *Riegel*, as well as the concurrence and the dissent. The *Riegel* case involved preemption of state common law tort suits regarding medical devices that have been FDA-approved under the PMA process.

The U.S. Supreme Court Decision

The *Riegel* case involved a catheter that had received PMA from the FDA to be marketed by Medtronic, Inc. as a Class III device.[96] The "device's labeling stated that use was contraindicated for patients with ... calcified stenoses," in other words, narrowed or constricted passages.[97] The patient, Charles Riegel, had a "diffusely diseased and heavily calcified" right coronary artery.[98] Riegel's doctor inflated the "catheter five times, to a pressure of 10 atmospheres," although the device's labeling "warned that the catheter should not be inflated beyond its rated burst pressure of eight atmospheres."[99] The catheter burst on the fifth inflation, and "Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery."[100] The patient and his wife raised New York state common law claims of "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter."[101]

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[92] President Obama, Memorandum for the Heads of Executive Departments and Agencies, Preemption (May 20, 2009).

[93] Pete Yost, *Bush Administration Uses Bureaucracy to Limit Lawsuits*, Law.com, May 14, 2008, http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202421377252. An FDA spokesperson stated that "[t]he preambles to these rules do not seek to preempt, but instead describe the scope of preemption under operation of federal law. *Id.* According to the article, "[j]udges have cited the FDA's regulatory preamble in its prescription drug rule in more than a dozen favorable rulings for pharmaceutical companies," although "judges have ruled for the consumers' right to sue about as often as they have ruled against them in cases touching on the regulatory preamble for prescription drug labels." *Id.*

[94] FDA, Preemption Review, 76 Fed. Reg. 61565 (Oct. 5, 2011).

[95] *Id.* at 61565.

[96] Riegel v. Medtronic, Inc., 552 U.S. 312, 310 (2008).

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] 552 U.S. at 320.

[101] *Id.*

The Supreme Court found that the Medical Device Amendments of 1976 (MDA) preempted state tort law claims because the common law negligence and strict liability claims fell into the category of "any requirement" in the bolded language below. Section 360k(a) of Title 21, United States Code (FFDCA § 521) reads:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use **any requirement**—
>
> (1) **which is different from or in addition to**, any requirement applicable under [federal law] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [relevant federal law].

In other words, the Court held that the federal government had established requirements in the PMA process for medical devices in the MDA. The Court said that the New York state common law claims were "different from or in addition to" the federal MDA requirements because "reference to a State's 'requirements' includes its common-law duties."[102]

To reach its holding, the Court addressed two questions: (1) Has the federal government established requirements applicable to the medical device? and (2) If the answer to the first question is yes, are the plaintiffs' common law claims (such as negligence in the design, labeling, and marketing of the catheter) based on state requirements that are "different from, or in addition to" the federal requirements, "and that relate to safety and effectiveness"?[103]

First, the Court held that the federal government had "established requirements applicable to" the device at issue, Medtronic's catheter, and that PMA "imposes 'requirements' under the MDA."[104] In making its determination, the Court distinguished its earlier decision in *Medtronic, Inc. v. Lohr*, which held that "federal manufacturing and labeling requirements" do not preempt common law claims of negligence and strict liability in instances where: (1) any federal requirements are not specific to the device at issue; and (2) the FDA finds that a device "is 'substantially equivalent' to another device exempt from premarket approval,"[105] because this constituted an exemption, not a "requirement."[106] The Court found that, unlike the substantial equivalence process, PMA is device-specific and is not an exemption, but rather a "requirement."[107] The Court differentiated from *Lohr* by reasoning that PMA is focused on safety, rather than equivalence; that PMA is a formal FDA review, as opposed to the lack of formal review that the device subject to premarket notification in *Lohr* received; and that devices that receive PMA may not deviate from the FDA-approved specifications in the PMA application.[108]

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[102] *Id.* at 324, 335.

[103] *Id.* at 321-22.

[104] *Id.* at 322-23.

[105] *Id.* at 317, 322.

[106] *Id.* at 322.

[107] *Id.* at 322-23.

[108] *Id.*

Second, the Court held that "New York's tort duties constitute 'requirements' under the MDA"[109] and that these "requirements" were "different from, or in addition to" the federal requirements. The Court began by noting that five Justices in *Lohr* "concluded that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements *specific* to a medical device."[110] The *Lohr* Court had said that it did "not believe that [the MDA's] statutory and regulatory language necessarily precludes ... 'general' state requirements from ever being pre-empted...."[111] In other words, the MDA could potentially preempt general state "requirements," or general state common law under circumstances such as strict liability, negligence, and implied warranty claims.[112]

The Court also addressed the Riegels' argument that general common law duties are not "requirements" specific to medical devices, and therefore should not be preempted. This argument depended on the FDA regulation 21 C.F.R. § 808.1(d)(1), which states "that MDA pre-emption does not extend to '[s]tate or local requirement of general applicability [whose] purpose ... relates either to other products in addition to devices.'"[113] However, the regulation also "states that the MDA sets forth a 'general rule' pre-empting state duties 'having the force and effect of law (whether established by statute, ordinance, regulation, or court decision).'"[114] It was this subsection of the regulation prompted the Court to note that only common law duties are established by court decision.[115]

Additionally, the Court undertook a discussion of the statutory text and informed Congress of the meaning that "this Court will assign to terms regularly used" in congressional enactments: "Absent other indication, reference to a State's 'requirements' includes its common-law duties."[116] The Court then remarked that "[i]n the present case, there is nothing to contradict the normal meaning" that the term "requirements" will include state common-law duties.[117] The Court then indicated that state tort law was perhaps "less deserving of preservation" than state statutes or state regulations, as one state jury could potentially "set state standards 'different from, or in addition to' federal standards."[118]

The Court held that New York's common law causes of action were preempted by the MDA "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal

[109] *Id.* at 323.

[110] *Id.* at 323-24 (emphasis added).

[111] *Id.* at 328 n.6 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 500 (1996)).

[112] *Id.* at 327. The *Riegel* Court also referred to two other cases—*Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—in which the Court held that statutory language regarding preemption of state "requirements" was the equivalent of preemption of state common law. *Riegel*, 552 U.S. 312, 324. In *Bates*, the Court stated: "A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 544 U.S. at 445. In *Cipollone*, the Court held that a preemption provision, which prohibited states from imposing any requirement or prohibition based on smoking and health with respect to the advertising or promotion of cigarettes that are labeling in conformity with the Federal Cigarette Labeling and Advertising Act, was intended to preempt some common law claims.

[113] 21 C.F.R. § 808.1(d)(1).

[114] 21 C.F.R. § 808.1(b).

[115] *Riegel*, 552 U.S. at 329.

[116] *Id*. at 324.

[117] *Id.*

[118] *Id.* at 325.

law."[119] To the extent that the lawsuit raises claims that "'parallel' rather than add to, federal requirements," such as a state "damages remedy for claims premised on a violation of FDA regulations," it does not appear that such suits would be preempted.[120]

Justice Stevens's Concurrence

Justice Stevens agreed with the dissent's "description of the actual history and principal purpose of the pre-emption provision at issue" and observed that the text of the provision "cover[s] territory not actually envisioned by its authors."[121] He also dispensed with congressional intent in this case: "we have frequently concluded that 'it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.'"[122] However, he agreed with the majority that New York common law duties "constitute requirements with respect to the device at issue that differ from federal requirements relating to safety and effectiveness."[123] He found that the preemption provision's language "encompasses other types of 'requirements'" and that "common-law rules administered by judges ... create and define legal obligations, [therefore] some of them unquestionably qualify as 'requirements.'"[124]

Justice Ginsburg's Dissent

Justice Ginsburg's dissent focused on the intent of Congress in enacting the MDA, as well as previous Supreme Court cases emphasizing congressional intent as the "ultimate touchstone of pre-emption analysis."[125] The dissent tracks the Court's presumption against preemption analysis outlined earlier in this report and stated that "[w]here the text of a preemption clause is open to more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'"[126]

Beginning with the majority's holding that "[a]bsent other indication, reference to a State's 'requirements' includes its common law duties," she stated that "other indication[s]" exist in the MDA and its legislative history that preclude the Court's conclusion that the MDA preempts state common law claims.[127] Justice Ginsburg noted the act's consumer-oriented purpose, as well as congressional awareness of over 500 lawsuits related to the Dalkon Shield medical device: "I find informative the absence of any sign of a legislative design to preempt state common-law tort actions."[128] She pointed to the absence of a federal compensation scheme for consumers injured by FDA-approved medical devices as evidence that Congress did not intend to preempt state

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[119] *Id.* at 330.

[120] *Id.* The Court declined to address whether the Riegels raised parallel claims, as the Riegels did not make that argument in their briefs to the Second Circuit or in their petition for certiorari. *Id.*

[121] Riegel v. Medtronic, Inc., 552 U.S. 312, 331 (Stevens, J. concurring). Justice Stevens also noted that the majority opinion advanced several policy arguments regarding impediments to development of devices.

[122] *Id.* (quoting Oncale v. Sundowner Offshore Services, Inc., 523 U.S. 75, 79-80 (1998)).

[123] *Riegel*, 552 U.S. at 332 (Stevens, J. concurring).

[124] *Id.*

[125] *Riegel*, 552 U.S. at 334 (Ginsburg, J. dissenting) (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)).

[126] *Id.* at 335 (quoting Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005)).

[127] *Id.* at 335.

[128] *Id.* at 336-37.

common law suits.[129] Furthermore, she referenced the Court's plurality in *Lohr*, which stated: "[N]othing in the hearings, the Committee reports, or the debates ... suggest[ed] that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices."[130] Justice Ginsburg also cited remedies provided by the MDA—such as the FDA's ability to order a device manufacturer to repair or recall the device—and a provision stating that compliance with an FDA order to recall or repair a device "shall not relieve any person from liability under Federal or State law," as evidence that Congress did not intend to preempt state common law suits.[131]

With regard to the FDA's shift in its position on preemption, she took note of the FDA's pre-2003 view, as described by a former FDA counsel, that "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection ... [as] [e]ven the most thorough regulation of a product ... may fail to identify potential problems."[132] The dissent then addressed the deference that should be granted to the FDA's new position on preemption, finding that the agency's announcement of its position shift in an *amicus* brief would be entitled to little deference when compared with the FDA's previous view, the presumption against preemption, and the MDA itself.[133]

The dissent next examined the history of federal regulation of medical devices, and in part, federal regulation of drugs and additives. Justice Ginsburg noted that, prior to the enactment of the MDA in 1976, the defense of state common law claims for defective design or drug labeling either did not involve preemption or, if preemption was asserted as a defense, it was unsuccessful.[134] She argues that Congress included the preemption provision 21 U.S.C. § 360k "to empower the FDA to exercise control over state premarket approval systems installed at a time when there was no preclearance at the federal level," such as the California PMA system.[135] Moreover, unlike devices, states had not developed PMA processes for drugs or additives.[136]

The dissent also quotes the FDA's former counsel as observing the disparity that would arguably arise if preemption of state common law suits existed for devices with PMA, but not drugs or biologics: "This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress."[137] Medtronic had argued that "Congress would not have wanted state juries to second-guess the FDA's finding that a medical device is safe and effective when used as directed," however the dissent noted that the PMA process for drugs is "at least as rigorous" as that for devices, and that courts "have overwhelmingly held that FDA approval of a new drug

[129] *Id.* at 337.

[130] *Riegel*, 552 U.S. at 337 n.7 (Ginsburg, J. dissenting) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 491 (1996)).

[131] *Id.* at 339.

[132] *Id.* at 337-38 (quoting Porter, *supra* note 67, at 11).

[133] *Id.* at 338 n.8 (examining the deference that should be accorded to the FDA's position in light of the seminal Supreme Court administrative law cases *Skidmore v. Swift & Co.* and *United States v. Mead Corp*.).

[134] *Id.* at 340 n.11.

[135] *Id.* at 341-42.

[136] *Id.* at 342.

[137] *Id.* at 340 n.12 (quoting Porter, *supra* note 67, at 11). The FFDCA is a statute with many similarities in how it regulates food, drugs, and devices. For example, the act's enforcement provisions are based on findings that a food, drug, or device is adulterated or misbranded. If a product is adulterated or misbranded, criminal and civil penalties may apply, and the agency may seek injunctions, seizures, and debarment.

application does not preempt state tort suits."[138] The decades in which state product liability suits for drugs and FDA approval coexisted may also be seen as an indication of congressional intent not to preempt such claims, according to the dissent.[139]

Finally, Justice Ginsburg notes that device manufacturers may have two defenses to state common law suits: implied preemption under the actual conflict theory (in other words a conflict between FDA PMA of a device and the plaintiff's case theory), and "a regulatory compliance defense based on the FDA's approval of the premarket application."[140] FDA approval could be used as "evidence that [the manufacturer] used due care in the design and labeling of the product."[141]

Legal Implications

This section addresses the types of cases that may be affected by the Court's decision in *Riegel*, identifies areas that would not be affected by this opinion, and discusses similar cases that the *Riegel* Court noted may arise in the future. The *Riegel* Court held that state common law tort claims "premised on a violation of FDA regulations," such as claims that a medical device was not manufactured according to the FDA specifications or safety processes, were not preempted by 21 U.S.C. § 360k since "the state duties in such a case 'parallel,' rather than add to, federal requirements."[142] For example, individuals would be able to bring suits alleging that a device manufacturer failed to comply with FDA requirements and that there manufacturer was negligent in designing, labeling, or manufacturing the device because the manufacturer did not follow what the FDA had approved.[143]

Riegel did not alter the Court's holding in *Lohr* that the FDA's determination that a device was substantially equivalent to one on the market did not preempt state common law claims regarding defective or negligent design or damages remedies "for violations of common-law duties when those duties parallel federal requirements."[144] The Court did not address preemption in the investigational device exemption context. Nor did the Court discuss preemption in the context of PMA supplements, which are applications "required for any change to a device subject to an approved application under [21 U.S.C. § 360e] that affects safety or effectiveness, unless such a change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice" detailing the change.[145]

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[138] *Id.* at 343-44.

[139] *Id.*

[140] *Id.* at 344-45.

[141] *Id.* at 345.

[142] *Riegel*, 552 U.S. at 330; Linda Greenhouse, *Justices Shield Medical Devices from Lawsuits*, N.Y. Times, Feb. 21, 2008, at A1.

[143] Transcript of Oral Argument at 33-34, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf.

[144] Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

[145] 21 U.S.C. § 360e(d)(6)(A)(i). Devices with PMA supplements include devices such as Medtronic's Sprint Fidelis pacemaker lead, which was recalled by the company since it was "more prone to developing potentially deadly fractures than an older lead called the Quattro." Barnaby J. Feder, *Medical Device Ruling Redraws Lines on Lawsuits*, N.Y. Times, Feb. 22, 2008, at C2.

Justice Ginsburg noted that "[t]he Court's holding does not reach an important issue outside the bounds of this case: the preemptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval."[146] This issue was also mentioned by Chief Justice Roberts and Justices Kennedy, Stevens, and Souter at oral argument: "[There could be a newly discovered risk that the FDA never knew about. And, nevertheless, the claim would be preemptive."[147] Justice Ginsburg also argued that manufacturers may lack the incentive to make their devices safer once they receive PMA because they "have permission to market this product as is."[148] Medtronic's counsel responded by arguing that the FDA could withdraw approval of a device already on the market if there was a safer device in existence or allow both the newer and safer device to coexist on the market with the older device that may have more risks for some patients.[149] Congressional critics argue that the FDA's initiation of withdrawal proceedings "can be a time consuming process," as the FDA "must establish that the product no longer meets the statute's safety and efficacy requirements."[150] Relatedly, these Members note that medical device clinical trials "will not identify all of the significant risks involved in the use of the device," and that rare risks "will emerge only when a device is released into a larger and more heterogeneous population."[151]

Preemption Jurisprudence

One preemption scholar, who commented that litigants and scholars alike see preemption jurisprudence as "a muddle, a mess," saw the ruling as part of a "framework for pre-emption jurisprudence" that the Supreme Court may be attempting to create.[152] An appellate and Supreme Court practice attorney also indicated that *Riegel* and similar cases "raise recurring issues, such as whether there is a presumption against pre-emption and, if so, when it applies and how strong it is, and how much deference courts should give to the federal agency's position."[153] Although the majority opinion in *Riegel* did not address the presumption against federal preemption of state law, the Court had addressed the presumption against preemption in *Lohr*:

> Although our analysis of the scope of the pre-emption statute must begin with its text ... our interpretation of that language does not occur in a contextual vacuum. Rather that interpretation is informed by two presumptions about the nature of pre-emption.... First,

[146] *Riegel*, 552 U.S. at 333 n.1 (Ginsburg, J. dissenting).

[147] Transcript of Oral Argument at 28 (Stevens, J. speaking), Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf; *see also id.* at 29 (Souter, J. speaking); *id.* at 26-27 (Chief Justice Roberts: "What if the FDA hasn't done it [weighed safety and effectiveness of a device versus availability]? How are newly discovered flaws dealt with? I mean, say where you have this catheter, and the FDA didn't look at the possibility of allergic reactions to the balloon plastic, and all of a sudden it turns out to be a serious problem. How can you say that that's preemptive?" Mr. Olson [Counsel for Medtronic, Inc.]: "This is a continuous process. Information must be given by the manufacturer. There is a process by which doctors report consequences to the FDA. Citizens may report information." Justice Kennedy: "Is the manufacturer free to continue to sell the device after newly discovered risks ... pending the FDA's acting on the same information?" Mr. Olson: "Yes, Justice Kennedy.")

[148] *Id.* at 35-36.

[149] *Id.* at 36.

[150] Brief for Amici Curiae Senator Kennedy and Congressman Waxman, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *19-*20.

[151] *Id.* at *19.

[152] Coyle, *supra* note 39.

[153] *Id.*

> because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.... Second, our analysis of the scope of the statute's pre-emption is guided by our oft-repeated comment ... that 'the purpose of Congress is the ultimate touch-stone' in every pre-emption case.[154]

Given that the *Riegel* Court did not address this traditional presumption against preemption, it could be argued that the presumption may not be as strong as previously considered.[155] However, it is important to note that the Court did not explicitly repudiate this presumption.

The Riegels had argued "that the justices have relied repeatedly on the presumption that a federal statute does not pre-empt the historic police powers of the state absent a finding of Congress' 'clear and manifest intent' to do so," and that the statutory language did not contain such intent.[156] However, "a review of the Supreme Court's various preemption holdings demonstrates that the presumption is not applied in 'all pre-emption cases,' ... and that congressional intent is certainly not the 'ultimate touchstone' in every preemption case."[157]

The FDA and Preemption Cases

This section will examine the type of deference that the agency's shifting position on preemption would likely receive if addressed by a reviewing court. The Court looked to the text of the statute when considering the FDA's own interpretation of the statute's meaning. Initially, commentators on the case predicted that the amount of deference that the Court would give to the agency's position, given the FDA's reversal in favor of preemption circa 2003-04, would be a key question, as an agency interpretation "which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference than a consistently held agency view.'"[158] However, jurists may use various tools of interpretation, and the Supreme Court appeared to circumvent this question by finding clear congressional intent in favor of preemption. The Court "found it unnecessary to rely upon th[e] agency view [in support of preemption] because we think the statute itself speaks clearly to the point at issue."[159] Thus, the FDA regulation did not appear to affect how the Court chose to interpret the statute.

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[154] Medtronic, Inc. v. Lohr, 518 U.S. 470, 485-86 (1996).

[155] While Justice Ginsburg's dissent does not criticize the Court for omitting a discussion of this presumption, she outlines the Court's typical method of analyzing cases with this presumption. Riegel v. Medtronic, Inc., 552 U.S. 312, 334-35 (2008) (Ginsburg, J. dissenting).

[156] Coyle, *supra* note 39.

[157] *See* Jodie M. Gross and Judi Abbott Curry, *The Federal Preemption Debate in Pharmaceutical Labeling Product Liability Actions*, 43 TORT TRIAL & INSURANCE PRACTICE L. J. 35, 42 (Fall 2007), (quoting Retail Clerks Int'l Ass'n Local 1625 v. Schermerhorn, 375 U.S. 96, 103 (1963) ("[T]he purpose of Congress is the ultimate touchstone.")); Raymond, *supra* note 78, at 749 (arguing that "the Court has inconsistently approved the use of a background canon of interpretation providing for a 'presumption against preemption'" and stating that while the Court did not address the presumption in *Riegel*, it "relied heavily upon it" in a subsequent Supreme Court case involving preemption of tort suits related to drugs that have received FDA approval, "to deny preemption.").

[158] Immigration & Naturalization Serv. v. Cardoza-Fonseca, 480 U.S. 421, 447 n.30 (1987); *see, e.g.*, Greenhouse, *supra* note 44. With regard to the FDA's views on preemption in drug labeling products liability cases, see Gross and Curry, *supra* note 157, at 39, which discusses the conclusions of several courts "that FDA interpretations of its own statutes, as expressed in numerous amicus briefs as well as the preamble [to the regulation in which the FDA stated its belief that FDA approval of drug labeling preempts state law that conflicts or contradicts approved labeling], do not warrant *Chevron* deference."

[159] *Riegel*, 552 U.S. at 326.

However, the Court noted (and the dissent agreed with the type of deference that would be given) that if it "had found the statue ambiguous, and had accorded the agency's current position deference ... *Skidmore* deference would seemingly be at issue."[160] Under *Skidmore v. Swift & Co.*, "the weight of [an administrative agency's interpretation] will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."[161] The agency's lack of consistency in this area may have been a potential cause for concern, because while the FDA under the Bush Administration supported the concept of preemption, under previous Administrations the agency had taken the opposite view.[162]

Additionally, as noted above, since the Court's decision in *Riegel* was issued, the Obama Administration has directed executive departments and agencies to avoid including statements regarding intent to preempt state law through regulations or preambles to regulations.[163] It seems likely that courts will continue to address the scope of preemption with regard to FDA statutes and regulations. In two 2011 cases, the Supreme Court addressed deference to agency interpretations generally, although preemption was not at issue in these cases.[164]

Procedural Implications

In the wake of the *Riegel* decision, cases involving medical devices that received PMA from the agency have been dismissed for failure to state a "legally cognizable claim" that would "overcome[] a preemption defense."[165] These post-*Riegel* cases appear to have been affected by two other Supreme Court cases that address pleadings standards—*Bell Atlantic Corp. v. Twombly*,[166] which was decided a few months prior to *Riegel*, and *Ashcroft v. Iqbal*,[167] which was decided after *Riegel*. These two cases have been hailed by attorneys for defendant manufacturers and bemoaned by plaintiffs' attorneys for raising the plausibility requirements for pleadings.[168] Courts have found that plaintiffs with parallel state law claims did not "plead enough facts to 'state a claim that is plausible on its face'" and survive a motion to dismiss.[169] According to one

[160] *Id.* at 326.

[161] 323 U.S. 134, 140 (1944).

[162] *See, e.g.*, *Riegel*, 552 U.S. at 326-27.

[163] President Obama, Memorandum for the Heads of Executive Departments and Agencies, Preemption (May 20, 2009).

[164] In *Pliva, Inc. v. Mensing*, the Court deferred to THE FDA's interpretation of its regulations on drug labeling. 564 U.S. __ (2011), 131 S. Ct. 2567 (2011). In *Talk America, Inc. v. Michigan Bell Telephone Co*., the Court stated, "we defer to an agency's interpretation of its regulations, even in a legal brief, unless the interpretation is 'plainly erroneous or inconsistent with the regulation[s]' or there is any other 'reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question.'" 564 U.S. __ (2011), 131 S. Ct. 2254 (2011)(quoting Auer v. Robbins, 519 U.S. 452, 461, 462 (1997)).

[165] *See, e.g.*, Funk v. Stryker Corp., 631 F.3d 777, 779, 783 (5th Cir. 2011); Raymond, *supra* note 78, at 766-72.

[166] 550 U.S. 544 (2007).

[167] 556 U.S. 662 (2009).

[168] *See, e.g.*, Drug and Device Law Blog, http://druganddevicelaw.blogspot.com/search?q=TwIqbal+; Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L. J. 453 (2011).

[169] *Stryker Corp*., 631 F.3d at 782 (quoting Ashcroft v. Iqbal); *see* Frank-Jackson, *supra* note 168, at 477-79 (stating that "claims are dismissed because the pleaders lack details in their allegations about what specific federal law the medical device manufacturer violated," and that "courts readily dismiss claims where the plaintiff's complaint fails to [establish a causal] link [between] the federal violation [and] the injury sustained by the device recipient").

circuit judge from the United States Court of Appeals for the Eighth Circuit, "[t]he combination of the rigid application of *Twombly* and the now-articulated parallel claim exception to § 360k preemption have, in these cases, led to the dismissal of over two hundred potentially meritorious lawsuits on a technicality."[170] The significance of the pleading requirements in the context of medical device PMA preemption cases decided after *Riegel* has led one pro-plaintiff law professor to argue that Congress should amend the MDA to address "what is required for proper pleading" and *Twombly*'s "effect on plaintiff's claims."[171] Additionally, if a case survives a motion to dismiss, medical device manufacturers have argued that they should receive summary judgment from the courts under *Riegel*.[172]

In terms of the frequency of preemption post-*Riegel*, one law review article examined 75 post-*Riegel* lower court cases involving medical devices with FDA PMA.[173] The author defined rulings that "maintain[ed] a cause of action" as findings of no preemption, while preemption rulings were defined as (1) those that "dismiss[ed] all claims arising from the design, manufacture, and labeling of a medical device" and (2) dismissals of cases with claims that were "insufficiently pled" in terms of the necessary factual showings.[174] According to this study, courts found preemption in 77.3% of the cases.[175]

In terms of the types of claims that have survived post-*Riegel*, according to the article, in the 17 cases in which the courts did not find preemption, the courts considered three types of claims as "sufficiently parallel and not preempted": (1) "complaints arising from injuries suffered because of a design change without FDA approval"; (2) "claims that the manufacturer made express warranties to the consumer"; and (3) "claims of manufacturing defect."[176] While these types of claims were successful in some lower courts, they were not successful in others.[177] The author found that the first type of claim was an "infrequent factual occurrence" and that most plaintiffs would not be able to use this claim.[178] The second type of claim is based on contractual theories

[170] In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 23 F.3d 1200, 1210 (8th Cir. 2010)(Melloy, J. concurring in part and dissenting in part). The judge argued that "[i]f plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion [to dismiss]. In essence, application of *Twombly* in this manner eliminates the remaining exception to § 360(k) preemption." *Id.* at 1212.

[171] Frank-Jackson, *supra* note 168, at 495.

[172] *See, e.g.*, Dorsey v. Allergan, Inc. and Allergan Sales, LLC, 2009 U.S. Dist. LEXIS 26235 (D. Tenn. Mar. 11, 2009) (awarding summary judgment to the breast implant manufacturer on a strict liability claim because the silicone implants, a Class III device, later received FDA PMA, even though they had not received PMA at the time of the patient's surgery). *But see* Kavalir v. Medtronic, Inc., 2008 U.S. Dist. LEXIS 82979 (N.D. Ill. Aug. 27, 2008) (denying the medical device manufacturer's motion to dismiss the patient's claims of strict liability, breach of warranty, and breach of implied warranty with regard to an implantable cardioverter defibrillator device (ICD), a Class III device, because there was not a sufficient basis to determine whether the forms of the ICDs that received PMA were the same as the ones implanted in the plaintiff or whether the plaintiff's state tort claims were different from or in addition to FDA requirements).

[173] Raymond, *supra* note 78, at 757 (analyzing lower court cases from the date of the *Riegel* decision on February 20, 2008 through July 15, 2010).

[174] *Id.* at 758, 770-71.

[175] *Id.* at 760. The article also found that one state court "rejected" the *Riegel* decision in an opinion "explicitly calling for" congressional action. *Id.* at 756.

[176] *Id.* at 748, 766.

[177] *Id.* at 766.

[178] Raymond, *supra* note 78, at 766-67.

and may involve statements made by the manufacturer.[179] The "largest number of unpreempted parallel cases" were cases based on the third type of claim, such as those in which courts "determine[d] that the device at issue was not manufactured in conformance with the FDA's Current Good Manufacturing Practice and Quality System Regulation."[180] However, at least one federal appellate court found that such claims were preempted.[181]

The types of parallel claims that may survive in the lower courts may differ from circuit to circuit. The United States Court of Appeals for the Eighth Circuit has stated that "the contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined."[182] However, there may be some commonalities, and as more courts issue decisions on parallel claims post-*Riegel*, it may be easier to predict the types of parallel claims that courts will allow. According to one law review article, in five of the federal circuit courts, "in order for a parallel cause of action to be properly alleged, the claims must be premised on a violation of federal law or deviation from federal standard. Essentially, the circuit courts conclude the common law claims must go beyond alleging violation of federal statute, and the pleadings should contain sufficient detail of how the federal regulations were violated."[183]

Regulatory Implications

The Court's decision in *Riegel* has potential implications for the agency's responsibilities, regulatory authorities, and reliance on industry-provided information. The FDA's responsibilities have increased over the years, not only in the device area, but in other regulatory areas as well, including food, drugs, and tobacco. At the same time, the agency has been identified as strapped for resources and under strain because of the large amounts of responsibility it possesses.[184] While the *Riegel* decision does not grant the FDA greater responsibilities or authorities per se, it provides the FDA with more complete control over medical devices in the sense that the FDA's approval and regulatory requirements carry greater weight than state law requirements.[185] The Court's finding that the MDA preempts state common law claims related to devices that receive FDA PMA could conceivably pressure the FDA to more stringently examine devices undergoing the PMA process.[186] However, the FDA is not required to alter its considerations of devices undergoing the PMA process due to the effect that its approval would have in terms of preempting later consumer lawsuits, such as those with regard to defectively designed devices.

[179] *Id.* at 767-68.

[180] *Id.* at 768-69.

[181] *Id.* at 769-70; In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200 (8th Cir. 2010). Interestingly, the Eighth Circuit's decision was issued after Medtronic settled "all pending U.S. claims alleging product liability defects in its Sprint Fidelis defibrillator leads" in pacemakers. Alison Frankel, *8th Circuit Affirms Pre-emption Dismissal of Defibrillator Cases Against Medtronic*, American Lawyer, Oct. 21, 2010.

[182] *Sprint Fidelis*, 623 F.2d at 1204.

[183] Frank-Jackson, *supra* note 168, at 472.

[184] "The Institute of Medicine, the Government Accountability Office and the FDA's own science board have all issued reports concluding that poor management and scientific inadequacies have made the agency incapable of protecting the country against unsafe drugs, medical devices and food." Harris, *supra* note 60. The agency has countered that it is "responding to reports of its deficiencies and improving." *Id.*

[185] Supporters of the ruling, such as the Advanced Medical Technology Association, emphasize the FDA's "ultimate regulatory authority" with regard to medical devices, as opposed to multiple state regulation schemes and jury verdicts. Stephen Langel, *Democrats Threaten Legislation to Overturn Medical Device Ruling*, Congress Now, Feb. 21, 2008.

[186] Supporters have argued that the decision prevents "unscientific state juries second-guessing F.D.A.'s science-based decisions." Harris, *supra* note 60.

The agency's reliance on industry-provided information in the medical device area has led some to argue that consumers are more vulnerable post-*Riegel*.[187] The agency may decide to address the issue of notification from manufacturers who have discovered problems with their devices after receiving PMA. One former FDA Commissioner argues that once an FDA-approved product such as a drug has a wider distribution than in controlled clinical trials, it "may have a thousand times as many users," which can lead to increased numbers of adverse events such as illness or death, necessitating new warning labels or the withdrawal of the product from the market.[188] At oral argument, Justice Kennedy discussed the possibility of a notification requirement, along the lines of an adverse event reporting requirement,[189] for device manufacturers who have discovered safer alternatives: "If the manufacturer finds just from its own laboratory experiments and not because of any data it's [sic] received from doctors and patients that there's a better way to do this, does it have the obligation to notify the FDA? Mr. Olson: I don't think so, Justice Kennedy. I think that there may be marketplace incentives."[190]

Legislative Implications

Three potential legislative implications stem from the *Riegel* case. First, some Members of Congress introduced legislation in the 111th Congress to overturn the Court's decision. Second, if Congress decided not to nullify the effect of the *Riegel* decision through legislation, one congressional approach to offer a remedy to those injured by a medical device that has received FDA PMA would be to create a victim's compensation fund. Third, future legislation that references a state's "requirements" and state common law may be affected by the Court's statements in *Riegel*.

Legislative Proposals

In the 111th Congress, bills were introduced that would have overturned the Court's decision in *Riegel* by modifying the statute at issue: H.R. 1346, H.R. 4816, and S. 540. The House Energy and Commerce Committee's Subcommittee on Health held a hearing on H.R. 1346 in the 111th Congress. Similar legislation has not been introduced in the 112th Congress.

In response to the Supreme Court's decision in *Riegel*, Representative Pallone and Senator Kennedy introduced H.R. 1346/S. 540, the Medical Device Safety Act of 2009. The bill would have effectively overturned the Court's decision in *Riegel*. The bill would have modified 21 U.S.C. § 360k by adding a provision stating that "[n]othing in this section shall be construed to

[187] Harris, *supra* note 60.

[188] Donald Kennedy, *Misbegotten Preemptions*, 320 SCIENCE 585 (May 2, 2008).

[189] *See, e.g.*, 21 C.F.R. Part 803, Medical Device Reporting (For example, 21 C.F.R. § 803.50(a) requires manufacturers to report to the FDA, within 30 calendar days, information that the manufacturer "receive[s] or otherwise become[s] aware of ... from any source, that reasonably suggests that a device that [the manufacturer] market[s]: (1) May have caused or contributed to a death or serious injury; or (2) Has malfunctioned and this device or a similar device that [the manufacturer] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.").

[190] Transcript of Oral Argument at 36, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-179.pdf. Chief Justice Roberts noted that manufacturers must "disclose unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device"; however, this appears to differ from Justice Kennedy's observation regarding the obligation of a device manufacturer that has discovered or created a safer device than the one already on the market. *Id.* at 35-37.

modify or otherwise affect any action for damages or the liability of any person under the law of any State." The addition of that clause stated that the bill would "take effect as if included in the enactment of the [MDA]," and would "apply to any civil action pending or filed on or after the date of enactment of" the legislation, if passed. The language in H.R. 1346/S. 540 was incorporated in H.R. 4816, the Food and Drug Administration Improvement Act of 2010, in the 111th Congress, which was referred to committee but did not see further action.

The AARP, the American Association for Justice, the National Conference of State Legislatures, Public Citizen, state attorneys general, consumer groups, and several Members of Congress either supported the Riegels' case and/or support overturning the Court's decision, which some have argued impacts patients and states with strong consumer protection laws.[191] A former FDA chief counsel and the American Tort Reform Association opposed the legislation, and the latter reportedly called the bill "little more than an economic stimulus for personal injury lawyers."[192]

Creating a Victim's Compensation Fund

If Congress does not overturn the *Riegel* decision, but is interested in providing a remedy for injured medical device consumers, one approach would be to establish a compensation fund. In *Riegel*, the dissent argued that Congress would not have, "'without comment, remove[d] all means of judicial recourse' for consumers injured by FDA-approved devices."[193] The majority opinion responded by stating:

> It is not our job to speculate upon congressional motives. If we were to do so, however, the *only* indication available—the *text* of the statute—suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.[194] (emphasis added)

It could be argued that if Congress had intended to preempt state common law claims, it may have considered a victims' compensation fund of some sort.

In the past, Congress has created compensation schemes when it has removed an individual's ability to sue. For example, the National Vaccine Injury Compensation Program prohibits suits under state tort law against manufacturers and administrators of specified vaccines unless the claimant first files a claim for limited no-fault compensation with the National Vaccine Injury Compensation Program. Congress also created the September 11th Victim Compensation Fund of 2001, under which a victim or a victim's estate could seek no-fault compensation from the

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[191] Coyle, *supra* note 39; Anna Edney, *High Court Ruling Spurs New Debate on FDA Approvals*, Congress Daily PM, Feb. 22, 2008; Inside Washington Publishers, *Michigan Governor Calls for Reversal of Tough Preemption Law*, FDA Week, Feb. 1, 2008; Press Release, Public Citizen, Congress Must Pass Medical Device Safety Act, Restore Patient Access to Courts (Mar. 5, 2009), http://www.citizen.org/hot_issues/issue.cfm?ID=2180; Bill Swindell, *Trial Lawyers Lay Out Agenda for '09, Press Pre-Emption*, Congress Daily PM, Jan. 12, 2009.

[192] Marisa McQuilken, *House Hears Testimony on Medical Device Bill that Would Reverse Supreme Court Ruling*, National Law Journal, May 14, 2009.

[193] Riegel v. Medtronic, Inc., 552 U.S. 312, 337 (2008) (Ginsburg, J. dissenting).

[194] *Id.* at 326. Justice Scalia did note that "[c]ontrary to Justice Stevens' contention ... we do not 'advance' this argument [that the text of the statute is the only indication of congressional intent]. We merely suggest that if one were to speculate upon congressional purposes, the best evidence for that would be found in the statute." *Id.* at 326, n. 5.

program or bring a tort action against an airline or any other party, but could not do both, except to sue "any person who is a knowing participant in any conspiracy to hijack an aircraft or commit any terrorist act."[195]

Future Legislation Referencing a State's "Requirements" and State Common Law

The *Riegel* Court held that "[a]bsent other indication, reference to a State's 'requirements' includes its common law duties."[196] It appears that the Supreme Court arrived at this conclusion based on previous Supreme Court decisions addressing the term "requirements" in the state common law context, without relying on congressional intent, the FDA's own regulation,[197] or the agency's change in its position regarding preemption, which could be a motivation for congressional legislative action. Senator Kennedy and Representative Waxman argued in their *amicus* brief that the use of the term "requirement" in one statute—the Public Health Cigarette Smoking Act of 1969, which was at issue in the 1992 Supreme Court case *Cipollone v. Liggett Group*, *Inc*., and was interpreted by the Supreme Court to include common law tort claims—"does not mandate a conclusion that use of the same term in a very different statute with different goals means the same thing,"[198] as the MDA "was enacted by a different Congress at a different time."[199]

Based on this statement by the *Riegel* Court however, it appears that Congress and its legislative counsel should be aware of the use of the term "requirements" in existing statutes and proposed legislation.[200] This would appear to hold true regardless of congressional intent or when the statute was enacted, as the MDA was enacted approximately 16 years prior to the Court's analysis of the term "requirements" in *Cipollone*. It appears that Congress may have already recognized post-*Cipollone* that the use of the term "requirement" in a preemption provision could preempt product liability claims.[201] Thus, if Congress does not want to preempt state common law claims,

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[195] *See* CRS Report 95-797, *Federal Tort Reform Legislation: Constitutionality and Summaries of Selected Statutes*, by Vivian S. Chu; *see also* CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by Sarah A. Lister and C. Stephen Redhead (describing federal programs that "compensate or assist individuals who have suffered physical or psychological harm as a consequence of specific events (including the actions of others), or who have suffered specific types of physical or psychological harm").

[196] *Riegel*, 552 U.S. at 324.

[197] *Id.* at 327-29. "Even assuming that this regulation could play a role in defining the MDA's preemptive scope, it does not provide unambiguous support for the Riegels' position." *Id.* at 328. "All in all, we think that § 808.1(d)(1) can add nothing to our analysis but confusion. Neither accepting nor rejecting the proposition that this regulation can properly be consulted to determine the statute's meaning; and neither accepting nor rejecting the FDA's distinction between general requirements that directly regulate and those that regulate only incidentally; the regulation fails to alter our interpretation of the text insofar as the outcome of this case is concerned." *Id.* at 329. In contrast, the *Riegel* Court recognized that "[i]n *Lohr*, a majority of this Court interpreted the MDA's pre-emption provision in a manner 'substantially informed' by the FDA regulation set forth at 21 CFR § 808.1(d)." *Id.* at 322.

[198] Brief for Amici Curiae Senator Kennedy and Congressman Waxman, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *7-*8.

[199] *Id.* at *15.

[200] *See* Linda Greenhouse, *Supreme Court Hears Medical Device Case*, N.Y. Times, Dec. 5, 2007, at C3.

[201] Brief for Amici Curiae Senator Kennedy and Congressman Waxman, Riegel v. Medtronic, Inc., 552 U.S. 312 (2008); 2007 U.S. S. Ct. Briefs LEXIS 644, at *17 (noting that post-*Cipollone*, "Congress began explicitly stating in statutes that the term 'requirement' in preemption provisions did not preempt product liability actions. In two amendments to the FFDCA since 1992, in which Congress preempted state 'requirements,' Congress explicitly stated that product liability cases were not preempted.").

it may be advisable to provide a specific exemption for such claims when it uses the term "requirements" in the preemption context. Congress could consider inserting savings clauses to preserve state common law claims, such as those discussed in *Geier v. American Honda Motor Co*.[202] and *Sprietsma v. Mercury Marine*.[203]

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[202] 529 U.S. 861 (2000). In *Geier*, the Supreme Court held that a federal motor vehicle safety standard preempted a state common law action against a manufacturer for negligence for failure to equip a vehicle with a driver's side airbag. According to the Court, the express preemption provision of the National Traffic and Motor Vehicle Safety Act, which prohibits states from applying "any safety standard" different from an applicable federal standard, did not by itself preempt the state tort action. *Id.* at 865, 867. Preemption by statute was inconsistent with the statute's "saving clause," which provides that "compliance with" a federal safety standard "does not exempt any person from any liability under common law." *Id.* at 868. This saving clause, however, did not foreclose or limit the operation of ordinary preemption principles governing override of state laws—including common law tort rules—that conflict with federal statutes or regulations. Rather, the Court held, application of the tort rule would actually conflict with the vehicle safety standard because it would operate to frustrate the objectives of the federal regulation.

[203] Unlike the decision in *Geier*, however, the Court's pronouncement on federal preemption of a state tort law claim in *Sprietsma v. Mercury Marine* upheld the common law action in the face of a preemption challenge. 537 U.S. 51 (2002). In *Sprietsma*, the Court held that the Federal Boat Safety Act of 1971 does not preempt a state common law tort action for damages from the manufacturer of an outboard motor not equipped with a propeller guard. The statute contained an express preemption clause prohibiting states from adopting or enforcing "a law or regulation ... not identical to a regulation prescribed under [the Act]." *Id.* at 59. No federal regulation requires propeller guards on outboard motors; the Coast Guard studied the matter and decided not to issue a regulation. Using basic principles of statutory construction, the Court concluded that the statute's preemption language did not encompass common law claims. The Court found that the statute's saving clause, providing that compliance with the federal standards or regulations "does not relieve a person from liability at common law," supported this conclusion. *Id.*

FDA Regulation of Medical Devices

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December 28, 2011

Congressional Research Service
7-5700
www.crs.gov
R42130

CRS Report for Congress
Prepared for Members and Committees of Congress

c11173008

Summary

Prior to and since the passage of the Medical Device Amendments of 1976, Congress has debated how best to ensure that consumers have access, as quickly as possible, to new and improved medical devices and, at the same time, prevent devices that are not safe and effective from entering or remaining on the market. Medical devices regulation is complex, in part, because of the wide variety of items that are categorized as medical devices; examples range from a simple tongue depressor to a life-sustaining heart valve. The regulation of medical devices can affect their cost, quality, and availability in the health care system.

In order to be legally marketed in the United States, many medical devices must be reviewed by the Food and Drug Administration (FDA), the agency responsible for protecting the public health by overseeing medical products, including devices. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. CDRH activities are funded through a combination of public money (i.e., direct FDA appropriations from Congress) and private money (i.e., user fees collected from device manufacturers) which together comprise FDA's total. User fees account for 33% of FDA's total FY2011 program level and 15% of CDRH's program level, which is $378 million in FY2011 including $56 million in user fees. FDA's authority to collect user fees, originally authorized in 2002 (P.L. 107-250), has been reauthorized in five-year increments. It will expire on October 1, 2012, under the terms of the Medical Device User Fee Act of 2007 (MDUFA), Title II of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).

FDA requires all medical product manufacturers to register their facilities, list their devices with FDA, and follow general controls requirements. FDA classifies devices according to the risk they pose to consumers. Premarket review is required for moderate- and high-risk devices. There are two paths that manufacturers can use to bring such devices to market. One path consists of conducting clinical studies, submitting a *premarket approval* (PMA) application and requires evidence providing reasonable assurance that the device is safe and effective. The other path involves submitting a *510(k) notification* demonstrating that the device is *substantially equivalent* to a device already on the market (a *predicate device*) that does not require a PMA. The 510(k) process results in FDA *clearance* and tends to be much less expensive and less time-consuming than seeking FDA approval via PMA. Substantial equivalence is determined by comparing the performance characteristics of a new device with those of a predicate device; clinical data demonstrating safety and effectiveness are usually not required. Once approved or cleared for marketing, manufacturers must comply with regulations on manufacturing, labeling, surveillance, device tracking, and adverse event reporting.

Problems related to medical devices can have serious consequences for consumers. Defects in medical devices, such as artificial hips and pacemakers, have caused severe patient injuries and deaths. In 2006, FDA reported 116,086 device-related injuries, 96,485 malfunctions, and 2,830 deaths; an analysis by the National Research Center for Women & Families claims there were 4,556 device-related deaths in 2009. Reports published in 2009 through 2011—by the Government Accountability Office (GAO), the Department of Health and Human Services Office of the Inspector General and the Institute of Medicine—have voiced concerns about FDA's device review process. In 2009 and 2011 GAO included FDA's oversight of medical products on the GAO list of high-risk areas. FDA has conducted internal reviews as well and is implementing changes.

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Introduction

Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical devices. They may be simple tools used during medical examinations, such as tongue depressors and thermometers, or high-tech life-saving implants like heart valves and coronary stents. The medical device market has been characterized as including eight industry sectors: surgical and medical instrument manufacturing, surgical appliance and supplies, in vitro diagnostic products (IVDs, or laboratory tests), electromedical and electrotherapeutic apparatus, irradiation apparatus, dental equipment and supplies, ophthalmic goods, and dental laboratories.[1]

The federal agency primarily responsible for regulating medical devices is the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS). A manufacturer must receive FDA permission before its device can be legally marketed in the United States. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. Another center, the Center for Biologics Evaluation and Research (CBER), regulates devices associated with blood collection and processing procedures, cellular products and tissues.[2]

CDRH activities are funded through a combination of public money (i.e., direct FDA appropriations from Congress) and private money (i.e., user fees collected from device manufacturers) which together comprise FDA's total.[3] User fees may be used only to support product review activities, not other CDRH activities. User fees account for 33% of FDA's total FY2011 program level and 15% of CDRH's program level, which is $378 million in FY2011 including $56 million in user fees.[4] Congress has reauthorized in five-year increments FDA collection of medical device user fees; authority will expire on October 1, 2012 under the terms of the Medical Device User Fee Act of 2007 (MDUFA), Title II of the FDA Amendments Act of 2007 (FDAAA, P.L. 110-85).

Congress has historically been interested in balancing the goals of allowing consumers to have access, as quickly as possible, to new and improved medical devices with preventing devices that are not safe and effective from entering or remaining on the market. The goals of device availability and device safety may exert opposite pulls, with implications for consumers, the health care system, and the economy.

Investment in medical device development reportedly reached a high of $3.690 billion in 2007. Investment has slowed somewhat to $2.380 billion in 2010, and $1.510 billion in the first two quarters of 2011.[5] According to one report, the medical technology industry is a "vibrant and

[1] The Lewin Group, for AdvaMed, *State Economic Impact of the Medical Technology Industry,* June 7, 2010, p. 19.

[2] Jurisdiction of the centers' medical device review is governed by the FDA Intercenter Agreement between CBER and CDRH (October 31, 1991). FDA, *Devices Regulated by the Center for Biologics Evaluation and Research*, http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/510kProcess/ucm133429.htm.

[3] For more information on FDA's budget, see CRS Report R41737, *Public Health Service (PHS) Agencies: Overview and Funding, FY2010-FY2012*, coordinated by C. Stephen Redhead and Pamela W. Smith; and, CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson.

[4] FDA also funds some device and radiological health activities with fees collected under the Mammography Quality Standards Act (MQSA, P.L. 102-539), and device user fees fund some non–device-specific activities at FDA.

[5] PriceWaterhouseCoopers / National Venture Capital Association, "Medical Devices and Equipment," *Money Tree*
(continued...)

growing contributor to the U.S. economy, generating US$197 billion in revenue and employing over a half million workers in 2009 alone."[6] "Medical technology industry" includes "medical device, diagnostic, drug delivery and analytic/life science tool companies but excludes distributors and service providers" such as contract research or contract manufacturing organizations.[7] Another analysis found that "32 of the 46 medical technology companies with more than $1 billion in annual revenue are based in the United States."[8] Although the largest companies dominate the market for devices in terms of sales, it is often the small device companies that make a significant contribution to early innovation. Small companies may partner with larger companies to bring products to market if they lack access to the capital and resources to conduct clinical trials and navigate regulatory and reimbursement hurdles.

Manufacturers make decisions about pursuing new devices based in part on the cost of their development. Additional regulatory requirements may escalate these costs, while other incentives, such as tax breaks or market exclusivity extensions, may diminish them. If the device development cost is too high, the eventual result may be that consumers are denied access because new products are not developed or brought to market. Access problems have led to proposals for, and the enactment of, incentives to develop medical devices for rare diseases and pediatric populations. However, if the regulation and oversight of device development are not stringent enough, unsafe or ineffective products may reach the market and cause harm to consumers.

Problems related to medical devices can have serious consequences for consumers. Defects in medical devices, such as artificial hips, pacemakers, defibrillators, and stents, have caused severe patient injuries and deaths.[9] In 2006, FDA reported 116,086 device-related injuries, 96,485 malfunctions, and 2,830 deaths; a more recent independent analysis claims there were 4,556 device-related deaths in 2009.[10] Consequences such as these have raised questions as to whether adequate enforcement tools, resources, and processes are in place to ensure that marketed devices are safe. Reports by the Government Accountability Office (GAO), the Department of Health and Human Services Office of the Inspector General, and the Institute of Medicine (IOM) have voiced concerns about FDA's device review process.[11] In 2009 and in 2011 GAO included FDA's oversight of medical products on the GAO list of high-risk areas.[12]

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Report, data provided by Thomson Reuters, at http://www.pwcmoneytree.com.

[6] Ernst and Young. 2010. *Pulse of the industry: Medical technology report*, p. 15.

[7] Ibid., p. 87.

[8] PwC (PricewaterhouseCoopers), *Medical Technology Innovation Scorecard: The race for global leadership*, January 2011, p. 8, http://www.pwc.com/us/en/health-industries/health-research-institute/innovation-scorecard.

[9] For example, see Barry Meier and Janet Roberts, "Hip implant complaints surge, even as the dangers are studied," *The New York Times*, August 22, 2011, pp. A1, A16; Information on recalls is available by searching the database at FDA, *Medical & Radiation Emitting Device Recalls*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

[10] FDA, CDRH Reports, OCD FY2006: FDA Goal 3-Improving Product Quality, Safety, and Availability Through Better Manufacturing and Product Oversight, at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129324.htm; and Statement of Diana Zuckerman, PhD, President of the National Research Center for Women & Families at the House of Representatives Briefing on Medical Devices, May 17, 2011, at http://www.center4research.org/2011/05/statement-of-diana-zuckerman-phd-president-of-the-national-research-center-for-women-families-at-a-house-of-representatives-briefing-on-medical-devices/.

[11] U.S. Government Accountability Office, *Medical Devices: FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*, GAO-09-190, January 2009; Daniel R. Levinson, *Adverse Event Reporting for Medical Devices*, Department of Health and Human Services, Office of (continued...)

This report provides a description of FDA's medical device review process divided into two parts: premarket requirements and postmarket requirements. **Appendix A** provides a brief history of laws governing medical device regulation and **Appendix B** provides a table of acronyms used in the report.

The Medical Device Review Process: Premarket Requirements

FDA requires all medical product manufacturers to register their facilities, list their devices with the agency, and follow general controls requirements.[13] FDA classifies devices according to the risk they pose to consumers. Many medical devices, such as plastic bandages and ice bags, present only minimal risk and can be legally marketed upon registration alone. These low-risk devices are deemed *exempt* from premarket review and manufacturers need not submit an application to FDA prior to marketing.[14] In contrast, most moderate- and high-risk devices must obtain the agency's permission prior to marketing. FDA grants this permission when a manufacturer meets regulatory premarket requirements and agrees to any necessary postmarket requirements which vary according to the risk that a device presents.[15]

There are two paths that manufacturers can use to bring their moderate- and high-risk devices to market with FDA's permission. One path consists of conducting clinical studies, submitting a *premarket approval* (PMA) application and requires evidence providing reasonable assurance that the device is safe and effective.[16] The PMA process is generally used for novel and high-risk devices and is typically lengthy and expensive. It results in a type of FDA permission called *approval.*

PMA vs. 510(k)

There is a fundamental difference between the PMA and 510(k) pathways. In a PMA review, FDA determines if the device is reasonably safe and effective for its intended use. In a 510(k) review, FDA determines if the device is substantially equivalent to another device whose safety and effectiveness may never have been assessed.

The other path involves submitting a *510(k) notification* demonstrating that the device is *substantially equivalent* to a device already on the market (a *predicate device*) that does not require a PMA.[17] The 510(k) process is unique to medical devices and results in FDA *clearance*.

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Inspector General, Washington, DC, October 2009; and, IOM (Institute of Medicine), *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011.

[12] GAO regularly reports on government operations that it identifies as high risk due to their greater vulnerability to fraud, waste, abuse, mismanagement or the need for transformation to address economy, efficiency or effectiveness challenges. See GAO, *High-Risk Series: An Update*, GAO-09-271, January 2009; and GAO, *High-Risk Series: An Update*, GAO-11-278, February 2011.

[13] (21 CFR 862-892).

[14] The term *manufacturer* is used throughout this report for simplicity, but regulations also apply to any person, organization, or sponsor that submits an application to FDA to market a device.

[15] *In vitro* diagnostic products (IVDs, or laboratory tests) have their own unique premarket requirements and are not discussed further in this report.

[16] This is somewhat similar to the process FDA uses to approve a new prescription drug. For more information, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

[17] To be a predicate, a device must have either been on the market before 1976 when the Medical Device Amendments (MDA) took effect, or it could have been cleared for marketing after 1976, but must have the same intended use as a (continued...)

Substantial equivalence is determined by comparing the performance characteristics of a new device with those of a predicate device. To be considered substantially equivalent, the new device must have the same intended use and technological characteristics as the predicate; clinical data demonstrating safety and effectiveness are usually not required. The manufacturer selects the predicate device to compare with its new device. However, FDA has the ultimate discretion in determining whether a comparison is appropriate.

According to a 2009 GAO report, of the more than 50,000 devices that were listed by manufacturers with FDA from FY2003 through FY2007, about 67% were exempt from premarket review; the remainder entered the market via the 510(k) process (31%), the PMA process (1%) or via other means.[18]

Device Classification

Under the terms of the Medical Device Amendments of 1976 (MDA, P.L. 94-295), FDA classified all medical devices that were on the market at the time of enactment—the *preamendment* devices—into one of three classes. Congress provided definitions for the three classes—Class I, Class II, Class III—based on the risk (low-, moderate-, and high-risk respectively) to patients posed by the devices.[19] Examples of each class are listed in **Table 1**. Device classification determines the type of regulatory requirements that a manufacturer must follow. Regulatory requirements for each class are described below in more detail. *General controls*, the minimum regulations that apply to all FDA regulated medical devices, include five elements:[20]

- *establishment registration*—such as manufacturers, distributors, repackagers and relabelers, and foreign firms;[21]
- *device listing*—listing with FDA of all devices to be marketed;
- good manufacturing practices (GMP)—manufacturing of devices in accordance with the Quality Systems Regulation (QSR);[22]
- *labeling*—labeling of devices or in vitro diagnostic products;[23] and
- *premarket notification*—submission to FDA of a premarket notification 510(k).

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device classified in the Code of Federal Regulations (CFR).

[18] U.S. Government Accountability Office, *Medical Devices: FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*, GAO-09-190, January 2009, p. 9.

[19] FFDCA §513(a)(1); see also 21 CFR §860.3(c). As of 2009, the agency has classified over 1,700 distinct types of devices. The device types are organized in the Code of Federal Regulations (CFR) in 16 *classification panels*, such as "cardiovascular devices" or "ear, nose, and throat devices." FDA, *Device Classification*, June 18, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm.

[20] See FDA, *General and Special Controls*, April 30, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

[21] 21 CFR 807.20

[22] 21 CFR 820

[23] 21 CFR 801 or 809.10.

Table 1. Medical Device Classification

Device Classification	Examples	Safety / Effectiveness Controls	Required Submission
Class I	elastic bandages, examination gloves, and hand-held surgical instruments	General Controls	-*Registration only* unless 510(k) specifically required
Class II	powered wheelchairs, infusion pumps, and surgical drapes	General Controls & Special Controls	-*510(k) clearance* unless exempt -*IDE possible*
Class III	heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators	General Controls & Premarket Approval	-*PMA approval* -*IDE probable*
	metal-on-metal hip joint, certain dental implants	General Controls	-*510(k) clearance*

Source: FDA, Overview of Medical Device Regulation, General and Special Controls, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

Note: IDE means investigational device exemption.

Class I devices are those under current law for which general controls "are sufficient to provide reasonable assurance of the safety and effectiveness of the device."[24] Many Class I devices are *exempt* from the premarket notification and/or the QSR requirements, though they still have to comply with the other general controls. A device is exempt if FDA determines that it presents a low risk of illness or injury to patients.[25]

Class II devices are those under current law "which cannot be classified as class I because the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device."[26] Class II includes devices that pose a moderate risk to patients, and may include new devices for which information or *special controls* are available to reduce or mitigate risk. Special controls may include special labeling requirements, mandatory performance standards, and postmarket surveillance. Currently "15% of all device types classified in Class II are subject to special controls."[27] Although most Class II devices require premarket notification via the 510(k) process, a few are exempt by regulation.[28]

Class III devices are those under current law which "cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device," and "cannot be classified as a class II device because insufficient information exists to determine that the special controls ... would provide reasonable assurance of [their] safety and effectiveness," and are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or present "a

[24] FFDCA §513(a)(1)(A).

[25] See 21 CFR 862 to 892.

[26] FFDCA §513(a)(1)(B).

[27] IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 40.

[28] FDA, Overview of Medical Device Regulation, Medical Device Classification, Class I/II Exemptions, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm.

potential unreasonable risk of illness or injury, [are] to be subject ... to premarket approval to provide reasonable assurance of [their] safety and effectiveness."[29]

In other words, general and/or special controls are not sufficient to assure safe and effective use of a Class III device. Class III includes devices which are life-supporting or life-sustaining, and devices which present a high or potentially unreasonable risk of illness or injury to a patient. New devices that are not classified as Class I or II by another means, are automatically designated as Class III unless the manufacturer files a request or petition for reclassification.[30]

Although most Class III devices require *premarket approval* (PMA), some Class III devices may be cleared via the 510(k) process. In fact, during the first 10 years following enactment of MDA, over 80% of postamendment Class III devices entered the market on the basis of 510(k) submissions showing substantial equivalence to preamendment devices.[31] According to FDA, these are "postamendment (i.e., introduced to the U.S. market after May 28, 1976) Class III devices which are substantially equivalent to preamendment (i.e., introduced to the U.S. market before May 28, 1976) Class III devices and for which the regulation calling for the premarket approval application has not been published in 21 CFR."[32] FDA explains the situation as follows:

> When FDA's medical device regulation program began in the late 1970s, FDA regulated over 100 Class III device types through the 510(k) program. The intent was that FDA's regulation would be temporary and that over time, FDA would decide to reclassify those device types (or regulations) into Class I or II, or to sustain the classification in Class III and call for PMA applications. The process of reclassification is described in FDA's regulations in Section 515 of the Federal Food, Drug and Cosmetic Act. Over the years, FDA has made progress in this original list; however, as of 2009, 26 medical device regulations remained in this transitional state awaiting final classification.[33]

At the time that the MDA of 1976 was drafted, "relatively few medical devices were permanently implanted or intended to sustain life. The 510(k) process was specifically intended for devices with less need for scientific scrutiny, such as surgical gloves and hearing aids."[34] Over time, FDA's 510(k) review process was "challenged as new devices changed more dramatically and became more complex."[35]

Examples of Class III devices that are still regulated via the 510(k) program include the metal-on-metal hip joint, certain dental implants, automated external defibrillator, electroconvulsive therapy device, pedicle screw spinal system, intra-aortic balloon and control system, and several

[29] FFDCA §513(a)(1)(C).

[30] FFDCA §513(f)(2).

[31] IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 81.

[32] FDA, Overview of Medical Device Regulation, General and Special Controls, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

[33] FDA, CDRH Transparency, 515 Program Initiative, at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm240310.htm.

[34] Diana M. Zuckerman, Paul Brown, and Steven Nissen, "Medical device recalls and the FDA approval process," *Archives of Internal Medicine*, Online publication 2011, p. E2.

[35] Ibid., p. E2.

device types related to pacemakers.[36] In late 2009, FDA implemented the 515 Program Initiative "to facilitate the final adjudication of these remaining Class III device types."[37]

Medical Device Marketing Applications

As stated above, in general, before a non-exempt medical device may be legally marketed, a manufacturer must submit to FDA either: a PMA application, and the agency *approves* the device; or, a 510(k) notification, and the agency *clears* the device. FDA makes its determination—either approval or clearance—based on information the manufacturer submits. The information that is required—in other words, the type of marketing application the manufacturer must make (if any)—is determined based on the *risk* that the device poses, if used according to the manufacturer's instructions. FDA typically evaluates more than 4,000 510(k) notifications and about 40 original PMA applications each year.[38]

The Food and Drug Administration Modernization Act of 1997 (FDAMA; P.L. 105-115) gave FDA the authority to establish procedures for meeting with manufacturers prior to preparing a submission.[39] The procedures aim to speed the review process by giving FDA and a manufacturer the opportunity to address questions and concerns about the device and/or the planned studies that will be used to support the marketing application before the studies are initiated and the application is submitted. Requests for these meetings have doubled over the past five years according to testimony by CDRH Director Jeffrey Shuren at a November 2011 Senate hearing.[40]

Generally speaking, under the Federal Food, Drug and Cosmetic Act (FFDCA), manufacturers

- are prohibited from selling an adulterated product;[41]
- are prohibited from misbranding a product;[42]
- must register their facility with FDA and list all of the medical devices that they produce or process (and a fee is now required under the terms of FDAAA);

[36] FDA, CDRH Transparency, 515 Program Status, at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm240318.htm.

[37] FDA, CDRH Transparency, 515 Program Initiative, at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm240310.htm.

[38] U.S. Congress, Senate Special Committee on Aging, *A Delicate Balance: FDA and the Reform of the Medical Device Approval Process*, Testimony of William Maisel, Deputy Center Director for Science, FDA/CDRH, 112th Cong., 1st sess., April 13, 2011.

[39] For guidance on the procedures established, see *Early Collaboration Meetings Under the FDA Modernization Act*; Final Guidance for Industry and CDRH Staff, February 28, 2001, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm.

[40] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Medical Devices: Protecting Patients and Promoting Innovation*, 112th Cong., 1st sess., November 15, 2011.

[41] A device is adulterated if it includes any filthy, putrid, or decomposed substance, or if it is prepared, packed, or held under unsanitary conditions. The FFDCA further states that a device is adulterated if its container contains any poisonous or deleterious substance, or if its strength, purity or quality varies significantly from what the manufacturer claims. For higher class devices, a device can be considered adulterated if it fails to meet performance requirements outlined in its approval, or if it is in violation of other Good Manufacturing Practice requirements.

[42] A device is misbranded when all or part of the labeling (i.e., the FDA-approved printed material providing information about the device) is false, misleading, or missing.

- must file the appropriate premarket submission with the agency at least 90 days before introducing a *non-exempt* device onto the market; and
- must report to FDA any incident that they are aware of that suggests that their device may have caused or contributed to a death or serious injury.

Under the terms of MDUFA (Title II of FDAAA), manufacturers must pay a fee for most types of submissions. In 2010, FDA charged $217,787 in user fees to review a PMA ($54,447 for smaller companies) and $4,007 to review a 510(k) submission ($2,004 for small companies).[43] GAO found that in 2005, the average cost for FDA to review a PMA was $870,000 and the average cost to review a 510(k) submission was $18,200.[44] According to CDRH Director Jeffrey Shuren, user fees collected under MDUFA "fund only about 20% of the device review program;" in contrast, users fees collected under the Prescription Drug User Fee Act (PDUFA) "account for about two-thirds of the drug review program's budget."[45]

510(k) Notification

In general, a 510(k) submission is required for a moderate-risk medical device that is not non-exempt from premarket review. A 510(k) could also be used for currently marketed devices for which the manufacturer seeks a new indication (e.g., a new population, such as pediatric use, or a new disease or condition), or for which the manufacturer has changed the design or technical characteristics such that the change may affect the performance characteristics of the device.

Between 1996 and 2009, more than 80% of the devices cleared by FDA using 510(k) notification were Class II devices, about 10% were Class I and less than 5% were Class III.[46] A 2009 GAO report found that 25% of the 10,670 Class II devices cleared by FDA in FY2003 through FY2007 were either implantable, life sustaining or presented significant risk to the health, safety, or welfare of the patient.[47] The agency cleared about 90% of 510(k) submissions reviewed during FY2003 through FY2007.[48]

As noted previously, the standard for clearance of a traditional 510(k) is substantial equivalence with a predicate device. A predicate device can be one of two things. It can be a previously cleared Class I or II device that does not require a PMA. It can also be preamendment Class III for which the agency has not issued regulations requiring a PMA. (PMAs, which are more rigorous submissions than 510(k)s, are discussed in the "Premarket Approval (PMA)" section.)

[43] FDA, "Medical Device User Fee Rates for Fiscal Year 2010," 74 *Federal Register* 38444-38449, August 3, 2009; http://edocket.access.gpo.gov/2009/E9-18456.htm.

[44] U.S. Government Accountability Office, *Medical Devices: FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*, GAO-09-190, January 2009.

[45] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Medical Devices: Protecting Patients and Promoting Innovation*, Testimony of Jeffrey Shuren, Director CDRH, FDA, 112th Cong., 1st sess., November 15, 2011, http://help.senate.gov/imo/media/doc/Shuren.pdf.

[46] IOM, *Public Health Effectiveness of the FDA 510(k) Clearance Process: Measuring Postmarket Performance and Other Select Topics*, Workshop Report, Washington, DC, 2011, pp. 12 and 78.

[47] U.S. Government Accountability Office, *Medical Devices: FDA should take steps to ensure that high-risk device types are approved through the most stringent premarket review process*, GAO-09-190, January 2009, p. 18.

[48] Ibid., p. 27.

A manufacturer may choose one of three types of 510(k) submissions for premarket clearance: traditional, special, or abbreviated.[49] A study of 510(k) submissions between 1996 and 2009 found that about 80% were traditional, 16% were special, and 3% were abbreviated.[50] For novel devices without a predicate, there is another alternative called the de novo 510(k) process.

2011 IOM Report on 510(k) Substantial Equivalence

"In practice, the assessment of substantial equivalence generally does not require evidence of safety or effectiveness of a device. Unlike the premarket approval (PMA) process, by law the 510(k) process, with some exceptions [see SMDA 1990], focuses solely on the determination of a device's substantial equivalence to a predicate device. According to the FDA and the Supreme Court, when the FDA finds a device substantially equivalent to a predicate device, it has done no more than find that the new device is as safe and effective as the predicate. It is important to note that devices on the market before the enactment of the 1976 Medical Device Amendments (MDA)—the origin of all predicate devices for the 510(k) process—have never been systematically assessed to determine their safety and effectiveness. Because the preamendment device to which equivalence was established was not itself reviewed for safety or effectiveness, the committee found that clearance of a 510(k) submission was not a determination that the cleared device was safe or effective." See p. 154.

In a traditional 510(k), the manufacturer submits information about the performance of the device under specific conditions of use. It also contains information about the design of the device, characteristics of device components, representations of packaging and labeling, a description and summary of the non-clinical and clinical studies that were done to support the device performance characteristics, a description of means by which users can assess the quality of the device, and information about any computer software or additional or special equipment needed. Several administrative forms are also required.[51]

Most of the studies supporting a 510(k) submission are not clinical studies. Substantial equivalence, in many cases, means only that the device performs in a similar fashion to the predicate under a similar set of circumstances. As a result, many devices never have to demonstrate safety and effectiveness through clinical studies.

In addition to not requiring clinical studies, three other characteristics of the 510(k) process make it much less rigorous than the PMA process: (1) premarket inspections of how devices were manufactured are generally not required by FDA; (2) postmarket studies are not required by FDA as a condition of clearance; and, (3) FDA has limited authority to rescind or withdraw clearance if a 510(k) device is found to be unsafe or ineffective.[52]

FDA may take any of the following actions on a 510(k) after conducting its review:

- find the device substantially equivalent to the predicate and issue a clearance letter;

[49] FDA, Medical Devices, 510(k) Submission Methods, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm

[50] IOM, *Public Health Effectiveness of the FDA 510(k) Clearance Process: Measuring Postmarket Performance and Other Select Topics*, Workshop Report, Washington, DC, 2011, pp. 12 and 79.

[51] FDA, *How to Prepare a Traditional 510(k)*, September 14, 2009; http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134572.htm#link_4.

[52] Diana M. Zuckerman, Paul Brown, and Steven Nissen, "Medical device recalls and the FDA approval process," *Archives of Internal Medicine*, Online publication 2011, p. E4.

- find the device not substantially equivalent (NSE) and issue an NSE letter prohibiting marketing;
- determine that the device is exempt from a 510(k) submission;
- request additional information (with the final clearance decision pending review of that information).[53]

A manufacturer generally has 30 days to provide any additional information, or FDA may issue a notice of withdrawal of the application.54 The manufacturer may, at any time, withdraw its 510(k). FDA has 90 days to review a traditional 510(k).[55]

Abbreviated and special 510(k)s were new approaches to premarket notification that came from FDAMA. These approaches were intended to streamline and expedite FDA's review for routine submissions meeting certain qualifications, thus leaving reviewer time for more complicated submissions.

An abbreviated 510(k) uses guidance documents developed by FDA to communicate regulatory and scientific expectations to industry. Guidance documents have been prepared for many different kinds of devices, and are available on FDA's website. All guidance documents are developed in accordance with Good Guidance Practices (GGP), and many with public participation or opportunities for public comment.[56] In addition to issuing guidance documents, FDA can either develop performance or consensus standards or 'recognize' those developed by outside parties.[57] In an abbreviated 510(k), the manufacturer describes what guidance document, special control, or performance standard was used, and how it was used to assess performance of their device. Other minimum required elements are the product description, representative labeling, and a summary of the performance characteristics. FDA typically reviews an abbreviated 510(k) in 60 days.

A special 510(k) may be used for a modification to a device that has already been cleared; it typically uses the design control[58] requirement of the Quality System Regulation (QSR). The QSR describes the good manufacturing practice (GMP) requirements for medical devices.[59] The special 510(k) allows the manufacturer to declare conformance to design controls without providing the data. This type of submission references the original 510(k) number, and contains information about the design control requirements. FDA aims to review most special 510(k)s in 30 days.

[53] 21 CFR 807.100(a).

[54] 21 CFR 807.87(l).

[55] The FDA time clock (i.e., review cycle) begins when FDA receives the 510(k) and ends with the date that FDA issues either a request for additional information or a decision. More than one cycle may occur before FDA issues its final decision.

[56] 21 CFR 10.115. FDA continually accepts public comment on any draft or final guidance document.

[57] 21 CFR 861.

[58] Design controls are a series of predetermined checks, verifications, and specifications that are built into the manufacturing process to validate the quality of the product throughout the process. These can include defining the personnel responsible for implementing steps in the development and manufacturing process, defining specifications and standards for assessing the quality of the materials that go into making the product, designing specifications for accepting and rejecting different batches or lots of final product, and requirements for maintaining appropriate records.

[59] 21 CFR 820.30.

Under the FFDCA, novel devices lacking a legally marketed predicate are automatically designated Class III. FDAMA amended FFDCA Section 513(f) to allow FDA to establish a new, expedited mechanism for reclassifying these devices based on risk, thus reducing the regulatory burden on manufacturers. The de novo 510(k), though requiring more data than a traditional 510(k), often requires less information than a premarket approval (PMA) application.

In a de novo 510(k) process, the manufacturer submits a traditional 510(k) for its device. However, because there is no predicate device or classification, the agency will return a decision of not substantially equivalent. Within 30 days, the manufacturer submits a petition requesting reclassification of its device into Class II or I, as appropriate. Within 60 days, FDA will render a decision classifying the device according to criteria in FFDCA Section 513(a)(1). With approval, FDA issues a regulation that classifies the device. If the device is Class II, a special controls guidance document is also developed that then allows subsequent manufacturers to submit either traditional or abbreviated 510(k)s.[60] On September 30, 2011, FDA released draft guidance designed to further streamline the de novo review process.[61]

Premarket Approval (PMA)

A PMA is the most stringent type of device marketing application required by FDA for new and/or high-risk devices. PMA approval is based on a determination by FDA that the application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).[62] In contrast to a 510(k), PMAs generally require some clinical data prior to gaining approval.[63] All clinical evaluations of investigational devices (unless exempt) must have an investigational device exemption (IDE) before the study is initiated.[64] An IDE allows an unapproved device (most commonly an invasive or life-sustaining device) to be used in a clinical study to collect the data required to support a PMA submission.[65] The IDE permits a device to be shipped lawfully for investigation of the device without requiring that the manufacturer comply with other requirements of the FFDCA, such as registration and listing. In August and in November 2011 FDA released new draft guidance intended to ensure the quality of clinical trials and streamline the IDE process by clarifying the criteria for approving clinical trials.[66] All clinical studies must also receive prior approval by an institutional review board (IRB).[67]

[60] FDA, *New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff*, February 19, 1998, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm.

[61] Food and Drug Administration, "FDA Seeks Comment on Streamlined Review of Lower Risk, New Technology, Devices," press release, September 30, 2011, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm274008.htm.

[62] 21 CFR 814.

[63] PMAs can also use studies from the medical literature (a "paper PMA").

[64] See 21 CFR 812. Devices are exempt from IDE requirements when testing is noninvasive, does not require invasive sampling, does not introduce energy into a subject, and is not stand alone (i.e., is not used for diagnosis without confirmation by other methods or medically established procedures). See 21 CFR 812.2(c)(3).

[65] FDA, *Device Advice: Investigational Device Exemption (IDE)*, July 9, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm.

[66] FDA, "FDA seeks comment on proposed guidance for high-quality clinical studies," FDA, press release, August 15, 2011, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm268000.htm; and, "FDA issues two draft guidance documents to facilitate investigational medical device studies in humans," press release, November 10, 2011, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm279459.htm.

[67] An IRB is a group, generally comprised volunteers, that examines proposed and ongoing scientific research to ensure (continued...)

A PMA must contain (among other things) the following information:

- summaries of non-clinical and clinical data supporting the intended use and performance characteristics;
- detailed information on the device design and device components;
- instructions for use;
- representations of packaging and labeling;
- a description of means by which users can assess the quality of the device;
- information about computer software or additional or special equipment;
- literature about the disease and the similar devices; and,
- information on the manufacturing process.

Approval is based not only on the strength of the scientific data, but also on inspection of the manufacturing facility to assure that the facility and the manufacturing process are in compliance with the quality systems regulations (QSR).[68] FDAMA made it easier for manufacturers to submit the required sections of a PMA in a serial fashion as data are available ("modular PMA").

When a PMA is first received, FDA has 45 days to make sure the application is administratively complete. If not, the application is returned. If the application is complete, it is formally filed by FDA. The agency then has 75 days to complete the initial review and determine whether an advisory committee meeting will be necessary.

Advisory committees can be convened to make recommendations on any scientific or policy matter before FDA.[69] They are comprised of scientific, medical, and statistical experts, and industry and consumer representatives. An advisory committee meeting allows interested persons to present information and views at a public hearing.[70] FDA typically accepts advisory committee recommendations for an application (approvable, approvable with conditions, or non-approvable). However, there have been cases where FDA's decision has not been consistent with the committee's recommendation. CDRH will hold joint advisory committee meetings with other centers where necessary.

After FDA notifies the applicant that the PMA has been approved or denied, a notice may be published on the Internet announcing the data on which the decision is based and providing interested persons an opportunity to petition FDA within 30 days for reconsideration of the decision. Though FDA regulations allow 180 days to review the PMA and make a determination,

(...continued)

that human subjects are properly protected. For further information, see CRS Report RL32909, *Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule*, by Erin D. Williams.

[68] 21 CFR 820.

[69] For further information, see CRS Report RS22691, *FDA Advisory Committee Conflict of Interest*, by Erin D. Williams.

[70] 21 CFR 14.

total review time can be much longer.[71] MDUFA performance goals have been established to reduce the review time for PMAs.[72]

The Medical Device Review Process: Post-Market Requirements

Once approved or cleared for marketing, manufacturers of medical devices must comply with various regulations on labeling and advertising, manufacturing, postmarketing surveillance, device tracking, and adverse event reporting. This section describes those requirements and the Sentinel Initiative and the unique device identification (UDI) system, which are both under development, as well as CDRH compliance and enforcement actions.

Labeling

Like drugs and biological products, all FDA approved or cleared medical devices are required to be labeled in a way that informs a user of how to use the device. The FFDCA defines a "label" as a "display of written, printed, or graphic matter upon the immediate container of any article."[73] "Labeling" is defined as "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article" at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.[74]

The term "accompanying" is interpreted to mean more than physical association with the product; it extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, webpages, etc. Accompanying can also include labeling that is connected with the device after shipment or delivery for shipment in interstate commerce. According to an appellate court decision, "most, if not all advertising, is labeling. The term 'labeling' is defined in the FFDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[75]

[71] FDA, *FY2010 Performance Report to the Congress for the Medical Device User Fee Amendments of 2007*, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/MDUFMA/UCM243386.pdf. See also 21 CFR 814.40.

[72] FDA officials meet with industry leaders to agree upon mutually acceptable fee types, amounts, exceptions, and performance goals. The agreement specifies that, in return for the additional resources provided by medical device user fees, FDA is expected to meet performance goals defined in a letter, generally referred to as the "FDA Commitment Letter," from the HHS Secretary to the Chairmen and Ranking Minority Members of the Committee on Health, Education, Labor and Pensions of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives. This process is similar to the one used for prescription drug user fees under the Prescription Drug User Fee Act (PDUFA). For further information on PDUFA, see CRS Report RL33914, *The Prescription Drug User Fee Act (PDUFA): History, Reauthorization in 2007, and Effect on FDA*, by Susan Thaul.

[73] FFDCA §201(k)

[74] FFDCA §201(m)

[75] United States v. Research Laboratories, Inc., 126 F.2d 42 (9th Cir. 1942).

All devices must conform to the general labeling requirements.[76] Certain devices require specific labeling which may include not only package labeling, but informational literature, patient release forms, performance testing, and/or specific tolerances or prohibitions on certain ingredients.[77]

A section of the QSR also has an impact on various aspects of labeling.[78] The QSR regulation applies to the application of labeling to ensure legibility under normal conditions of use over the expected life of the device and also applies to inspection, handling, storage, and distribution of labeling. FDA considers a device to be adulterated if these requirements are not met. These requirements do not apply to the adequacy of labeling content, except to make sure the content meets labeling specifications contained in the device master record. However, failure to comply with GMP requirements, such as proofreading and change control, could result in labeling content errors. In such cases, the device could be misbranded and/or adulterated.

Manufacturing

Like drug manufacturers, medical device manufacturers must produce their devices in accordance with Good Manufacturing Practice (GMP). The GMP requirements for devices are described in the QSR.[79] The QSRs require that domestic or foreign manufacturers have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of non-exempt finished medical devices intended for commercial distribution in the United States. The regulation requires that various specifications and controls be established for devices; that devices be designed and manufactured under a quality system to meet these specifications; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed. FDA monitors device problem data and inspects the operations and records of device developers and manufacturers to determine compliance with the GMP requirements.[80] Though FDA has identified in QSR the essential elements that a quality system should have, manufacturers have a great deal of leeway to design quality systems that best cover nuances of their devices and the means of producing them.

Postmarketing Surveillance

The 2011 IOM report states that because "it is not possible to create a premarket review process that could completely ensure the safety of all devices before they enter the market, a strong surveillance system that monitors the safety of medical devices is essential. The identification of problems associated with a medical device can be an opportunity for various corrective actions."[81] Such actions might include changing the device labeling and instructions for use,

[76] 21 CFR 801

[77] 21 CFR 801.405 to 801.437. Denture repair kits, impact resistant lenses in sunglasses and eyeglasses, ozone emission levels, chlorofluorocarbon propellants, hearing aids, menstrual tampons, chlorofluorocarbons or other ozone depleting substances, latex condoms, and devices containing natural rubber.

[78] 21 CFR 820.120

[79] FFDCA §520; 21 CFR 820

[80] FDA, *Medical Devices: 1. The Quality System Regulation*, June 18, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/ucm122391.htm.

[81] IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, (continued...)

improving user training, or removal of the device from the market if appropriate. While the term postmarketing surveillance refers to a wide range of programs, the term postmarket surveillance refers to a specific activity defined in law.[82]

Postmarket Surveillance

For certain devices introduced into interstate commerce after January 1, 1991, manufacturers must conduct postmarket surveillance studies, once their device is approved or cleared for marketing, in order to gather safety and efficacy data. This requirement applies to devices that

- are permanent implants, the failure of which may cause serious adverse health consequences or death;
- are intended for use in supporting or sustaining human life; or
- present a potential serious risk to human health.

FDA may require postmarket surveillance for other devices if deemed necessary to protect the public health. The primary objective of postmarket surveillance is to study the performance of the device after clearance or approval as it is used in the population for which it is intended—and to discover cases of device failure and its attendant impact on the patient. Manufacturers may receive notification that their device is subject to postmarket surveillance when FDA files (i.e., accepts) the submission, and again when a final decision is made. If notified, manufacturers must submit a plan for postmarket surveillance to FDA for approval within 30 days of introducing their device into interstate commerce. MDUFA authorized the appropriation of $25 million per year for Postmarket Studies and Surveillance.[83]

Adverse Event Reporting

The Safe Medical Devices Act of 1990 (SMDA, P.L. 101-629) required FDA to establish a system for monitoring and tracking serious adverse events that resulted from the use or misuse of medical devices.[84] The Medical Device Reporting (MDR) regulation is the mechanism that FDA and manufacturers use to identify and monitor significant adverse events involving medical devices, so that problems are detected and corrected in a timely manner. [85]

Device manufacturers are required to report to FDA (1) within 30 calendar days of acquiring information that reasonably suggests one of their devices may have caused or contributed to a death, serious injury, or malfunction and (2) within 5 working days if an event requires action other than routine maintenance or service to prevent a public health issue.[86] User facilities, such as hospitals and nursing homes, are also required to report deaths to both the manufacturer, if

(...continued)

July 2011, p. 99.

[82] FFDCA §522.

[83] 21 USC 355 note

[84] FFDCA §519(a)

[85] The searchable MDR database for devices is publically accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM.

[86] 21 CFR 803.10(c)(1) and 803.10(c)(2)

known, and FDA within 10 working days.[87] User facilities must report serious injuries to the manufacturers (or FDA if the manufacturer is unknown) within 10 working days.[88] User facilities must also submit annual reports to FDA of all adverse event reports sent to manufacturers or FDA in the past year.[89]

In August 2009, FDA published notice of a proposed rule, and a related draft guidance document, that would require manufacturers to submit MDRs to the agency in an electronic format.[90] According to FDA, the proposed regulatory changes would provide the agency with a more efficient data entry process that would allow for timely access to medical device adverse event information and identification of emerging public health issues. The device industry requested a longer timeframe to implement the changes.

An October 2009 HHS Office of Inspector General report raised a number of questions about adverse event reporting for medical devices.[91] The report found that CDRH does not consistently use adverse event reporting and made several recommendations about how it could better do so.

Medical Device Tracking

Manufacturers are required to track certain devices from their manufacture through the distribution chain when they receive an order from FDA to implement a tracking system for a certain type of device.[92] The purpose of device tracking is to ensure that manufacturers of these devices can locate them quickly once in commercial distribution if needed to facilitate notifications and recalls in the case of serious risks to health presented by the devices. FDA may issue a tracking order for any Class II or Class III device:

- the failure of which would be reasonably likely to have serious adverse health consequences;
- which is intended to be implanted in the human body for more than one year; or
- which is intended to be a life sustaining or life supporting device used outside a device user facility.[93]

FDA has issued orders to track 13 implantable devices (including silicone gel-filled breast implants, various joint prostheses, implantable pacemakers, implantable defibrillator, mechanical

[87] 21 CFR 803.10(a)(1)(i).

[88] 21 CFR 803.10(a)(1)(ii).

[89] 21 CFR 803.10(a)(2) and 803.33.

[90] FDA, "Proposed Rule, Medical Device Reporting: Electronic Submission Requirements," 74 *Federal Register* 42203-42217, August 21, 2009; and FDA, "Draft Guidance for Industry, User Facilities, and Food and Drug Administration Staff; eMDR—Electronic Medical Device Reporting; Availability," 74 *Federal Register* Page 42310, August 21, 2009.

[91] Daniel R. Levinson, *Adverse Event Reporting for Medical Devices*, HHS Office of Inspector General, OEI-01-08-00110, October 2009, http://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf.

[92] FDA, *Medical Device Tracking*, May 13, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/MedicalDeviceTracking/default.htm#link_2.

[93] 21 CFR 821

heart valves, and implantable infusion pumps) and four other devices that are used outside a device user facility.[94]

The Sentinel Initiative

Section 905 of FDAAA mandated that FDA create an active postmarket risk identification system.[95] Although the FDAAA language is focused on monitoring drugs, FDA is using its general authority to monitor all FDA-regulated products, including medical devices, after they have reached the market.[96] FDA launched the Sentinel Initiative in May 2008; once completed, it will be called the Sentinel System. FDAAA set goals that the new system must be able to access data on 25 million people by July 2010, a goal which FDA has met, and 100 million people by July 2012.[97] As of January 2011 FDA has the capacity to access data from the electronic health records of more than 60 million people.[98]

FDA is collaborating with institutions throughout the United States, including academic medical centers, healthcare systems and health insurance companies, who act as data partners in the system. Additional collaborators will include patient and healthcare professional advocacy groups, academic institutions and the medical products industry. As an example of data applicable to medical devices, "one Sentinel-related project identified, described, and evaluated potential US orthopedic-implant registries that could participate in the creation of a national network of such registries as part of the Sentinel Initiative. Data related to medical devices include rates of selected outcomes (for example, myocardial infarction and stroke), rates of infection, and rates of implant revision and reintervention."[99] According to FDA, the Sentinel Initiative aims to develop and implement a proactive system that will complement existing systems that the agency has in place to track reports of adverse events linked to the use of its regulated products.[100]

Unique Device Identification

A provision in FDAAA requires the HHS Secretary to promulgate regulations establishing a unique device identification (UDI) system.[101] When implemented, this new system will require

[94] A device user facility means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. A current list of the devices for which tracking is required can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/MedicalDeviceTracking/default.htm#link_2.

[95] FFDCA §505(k); 21 USC 355

[96] FFDCA §1003(b)(2)(c)

[97] U.S. Food and Drug Administration, *The Sentinel Initiative: Access to Electronic Healthcare Data for More Than 25 Million Lives*, July 2010, http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM233360.pdf.

[98] Rachel E. Behrman, Joshua S. Benner, and Jeffrey S. Brown, et al., "Developing the Sentinel System—A National Resource for Evidence Development," *The New England Journal of Medicine*, vol. 364, no. 6 (February 10, 2011), pp. 498-499. The Sentinel Initiative is focused on electronic claims data held by health plans. Importantly, the plans retain control over the patient-level data within their own data firewalls and provide only aggregated information to FDA.

[99] IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 106.

[100] Information on the current status of the Sentinel Initiative is available at http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm.

[101] FFDCA §519(f); 21 USC 360i

- the label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices;
- the unique identifier to be able to identify the device through distribution and use; and
- the unique identifier to include the lot or serial number if specified by FDA.

According to FDA, "incorporation of UDI into various health-related databases will greatly facilitate many important public health-related activities including: reducing medical errors; reporting and assessing device-related adverse events and product problems; tracking of recalls; assessing patient-centered outcomes and the risk/benefit profile of medical devices in large segments of the U.S. population; and, providing an easily accessible source of device identification information to patients and health care professionals."[102]

CDRH indicated in its FY2010 Strategic Priorities that the UDI system will be implemented by September 30, 2013.[103] UDI will be implemented in three phases: Class III devices will need to be in compliance within one year after the final rule is published, Class II at three years and Class I at five years after the final rule.[104] FDA has held a number of public meetings and workshops with stakeholders to discuss the adoption, implementation, and use of a UDI system. The agency has posted on its website information about these meetings as well as a number of reports on the use of UDI for medical devices.[105]

FDA has been working with the Global Harmonization Task Force (GHTF) to foster international harmonization in the regulation of medical devices through the development of non-binding guidance documents.[106] The GHTF is a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States, Canada, Japan and Australia. In September 2011 the GHTF published its final document on UDI for medical devices.[107]

Compliance and Enforcement

Compliance requirements apply to both the premarket approval process and postmarket surveillance. When a problem arises with a product regulated by FDA, the agency can take a number of actions to protect the public health. Initially, the agency tries to work with the manufacturer to correct the problem on a voluntary basis. If that fails, legal remedies may be

[102] FDA, "Unique Device Identification for Postmarket Surveillance and Enforcement; Public Workshop," 76 *Federal Register* 43691-43693, July 21, 2011.

[103] FDA, Center for Devices and Radiological Health, *CDRH FY 2010 Strategic Priorities*, p. 6, http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHVisionandMission/UCM197648.pdf.

[104] Alaina Bush, "CER, Safety uses eyed as part of FDA device identification rule," *Inside Health Reform*, vol. 3, no. 39 (September 22, 2011).

[105] Meeting information, reports and current status of the UDI system can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

[106] GHTF website is at http://www.ghtf.org/.

[107] GHTF SC UDI Ad Hoc Working Group, *Unique Device Identification (UDI) System for Medical Devices*, Global Harmonization Task Force, GHTF/AHWG-UDI/N2R3:2011, September 16, 2011, http://www.ghtf.org/documents/ahwg/AHWG-UDI-N2R3.pdf.

taken, such as: asking the manufacturer to recall a product, having federal marshals seize products, or detaining imports at the port of entry until problems are corrected. If warranted, FDA can ask the courts to issue injunctions or prosecute individual company officers that deliberately violate the law. When warranted, criminal penalties, including prison sentences, may be sought.

Section 516 of the FFDCA gives FDA the authority to ban devices that present substantial deception or unreasonable and substantial risk of illness or injury. Section 518 enables FDA to require manufacturers or other appropriate individuals to notify all health professionals who prescribe or use the device and any other person (including manufacturers, importers, distributors, retailers, and device users) of any health risks resulting from the use of a violative device, so that these risks may be reduced or eliminated. This section also gives consumers a procedure for economic redress when they have been sold defective medical devices that present unreasonable risks. Section 519 of the act authorized FDA to promulgate regulations requiring manufacturers, importers, and distributors of devices to maintain records and reports to assure that devices are not adulterated or misbranded. Section 520(e) authorizes FDA to restrict the sale, distribution, or use of a device if there cannot otherwise be reasonable assurance of its safety and effectiveness. A restricted device can only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation.

Inspection

Each FDA center has an Office of Compliance (OC) that ensures compliance with regulations while pre- or postmarket studies are being undertaken, with manufacturing requirements, and with labeling requirements. The objectives of CDRH's OC's Bioresearch Monitoring (BIMO) program are to ensure the quality and integrity of data and information submitted in support of IDE, PMA, and 510(k) submissions and to ensure that human subjects taking part in investigations are protected from undue hazard or risk. This is achieved through audits of clinical data contained in PMAs prior to approval, data audits of IDE and 510(k) submissions, inspections of IRBs and nonclinical laboratories, and enforcement of the prohibitions against promotion, marketing, or commercialization of investigational devices. Any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept, can be subject to inspection. (See **Table 2**.)

Table 2. CDRH, FDA Foreign and Domestic Inspections, FY2004–FY2010

FY	2004	2005	2006	2007	2008	2009	2010
Number of Inspections	2,936	2,694	2,691	2,495	2,353	2,550	3,174

Source: FDA Center for Devices and Radiological Health, Office of Compliance, Division of Risk Management Operations based on Center Ad Hoc Reporting System inspection data.

The OC also reviews the quality system design and manufacturing information in the PMA submission to determine whether the manufacturer has described the processes in sufficient detail and to make a preliminary determination of whether the manufacturer meets the QSR. If the manufacturer has provided an adequate description of the design and manufacturing process, a preapproval inspection can be initiated. Inspection is to include an assessment of the manufacturer's capability to design and manufacture the device as claimed in the PMA and confirm that the quality system is in compliance with the QSR. Postapproval inspections can be conducted within 8 to 12 months of approval of the PMA submission. The inspection is to

primarily focus on any changes that may have been made in the device design, manufacturing process, or quality systems.

The compliance offices work closely with the Office of Regulatory Affairs (ORA),[108] which operates in the field to regulate almost 124,000 business establishments that annually produce, warehouse, import and transport $1 trillion worth of medical products. Consumer safety officers (CSOs) and inspectors typically have conducted about 22,000 domestic and foreign inspections a year to ensure that regulated products meet the agency's standards. CSOs also monitor clinical trials. Scientists in ORA's 13 laboratories typically have analyzed more than 41,000 product samples each year to determine their adherence to FDA's standards.

Warning Letter

A warning letter is a written communication from FDA notifying a responsible individual, manufacturer, or facility that the agency considers one or more products, practices, processes, or other activities to be in violation of the laws that FDA enforces. The warning letter informs the recipient that failure to take appropriate and prompt action to correct and prevent any future repeat of the violations could result in an administrative or regulatory action. Although serious noncompliance is often a catalyst for issuance of a warning letter, the warning letter is informal and advisory.[109] (See **Table 3**.)

Table 3. CDRH Warning Letters Issued, FY2000–FY2010

FY	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Number of Letters	528	498	285	205	198	182	154	155	152	136	204

Source: FDA Center for Devices and Radiological Health, Office of Compliance, Division of Risk Management Operations based on Office of Regulatory Affairs Case Management System warning letter data.

Product Recall

A recall is a method of removing or correcting products that FDA considers are in violation of the law.[110] Medical device recalls are usually conducted voluntarily by the manufacturer after negotiation with FDA.[111] Manufacturers (including refurbishers and reconditioners) and importers are required to report to FDA any correction or removal of a medical device that is undertaken to reduce a health risk posed by the device.[112] A recall may be a total market withdrawal or may be of a portion of product (such as a single lot). In rare instances, where the manufacturer or

[108] See ORA at http://www.fda.gov/AboutFDA/CentersOffices/ORA/default.htm.

[109] Warning letters are publically available on FDA's website at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm.

[110] Recall does not include market withdrawal or a stock recovery. A market withdrawal is a firm's removal or correction of a distributed product for a minor violation that does not violate the law and would not be subject to legal action by FDA (e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.). Stock recovery involves correction of a problem before product is shipped (i.e., is still in the manufacturer's control).

[111] 21 CFR 7

[112] 21 CFR 806.

importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer.[113]

When a recall is initiated, FDA performs an evaluation of the health hazard presented taking into account the following factors, among others:

- Whether any disease or injuries have occurred from the use of the product;
- Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard;
- Assessment of hazard to various populations (e.g., children, surgical patients, pets, livestock) who would be exposed to the product;
- Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed;
- Assessment of the likelihood of occurrence of the hazard;
- Assessment of the consequences (immediate or long-range) of the hazard.

Following the health hazard assessment, FDA assigns the recall a classification according to the relative degree of health hazard. *Class I* recalls are the most serious, reserved for situations where there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death. *Class II* recalls are for situations where the use of, or exposure to, a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. In a *Class III* recall situation, the use of, or exposure to, a product is not likely to cause adverse health consequences. (See **Table 4**.) In addition to a warning letter or recall, FDA may issue a public notification or safety alert (e.g., "Dear Doctor" letter), to warn healthcare providers and consumers of the risk of the device.[114]

Table 4. CDRH Class I, II, and III Product Recalls, FY2004–FY2010

FY	2004	2005	2006	2007	2008	2009	2010
Class I	36	77	76	45	131	219	334
Class II	1,235	1,351	1,252	1,102	2,178	2,222	2,208
Class III	219	170	222	132	163	194	92

Source: FDA Center for Devices and Radiological Health, Office of Compliance, Division of Risk Management Operations based on Center Ad Hoc Reporting System recall data.

[113] 21 CFR 810. See out-of-print CRS Report RL34167, *The FDA's Authority to Recall Products*, by Vanessa K. Burrows (available from the author upon request).

[114] The main page for recalls, market withdrawals, and safety alerts for all FDA-regulated products is http://www.fda.gov/opacom/7alerts.html.

Appendix A. History of Laws Governing Medical Device Regulation

The Federal Food, Drug and Cosmetics Act of 1938

The first general federal food and drug law, the *Food and Drugs Act of 1906*, did not contain any provisions to regulate medical device safety or claims made regarding such devices. Strong support for reform developed during the 1930s due to "false therapeutic claims for medical devices [that] were being presented to the public through radio and newspaper advertising."[115] Medical devices came under federal scrutiny when Congress passed the *Federal Food, Drug and Cosmetic Act (FFDCA) of 1938* (P.L. 75-717). The regulatory authority provided to FDA by the 1938 law was "limited to action after a medical device has been offered for introduction into interstate commerce" and only when the device was deemed to be "adulterated or misbranded."[116]

Most of the legitimate devices on the market at the time the 1938 Act became law "were relatively simple items which applied basic science concepts such that experts using them could readily recognize whether the device was functioning properly; the major concern with respect to these devices was assuring truthful labeling."[117] During the first 20 years following enactment of the 1938 law, FDA's activity with respect to medical devices involved protecting the American public from *fraudulent* devices; FDA began to turn its attention to the hazards from *legitimate* devices around 1960.[118]

> The post-war revolution in biomedical technology had resulted in the introduction of a wide variety of sophisticated devices. New developments in the electronic, plastic, metallurgy, and ceramics industries, coupled with progress in design engineering, led to invention of the heart pacemaker, the kidney dialysis machine, defibrillators, cardiac and renal catheters, surgical implants, artificial vessels and heart valves, intensive care monitoring units, and a wide spectrum of other diagnostic and therapeutic devices. Although many lives have been saved or improved by the new discoveries, the potential for harm to consumers has been heightened by the critical medical conditions in which sophisticated modern devices are used and by the complicated technology involved in their manufacture and use. In the search to expand medical knowledge, new experimental approaches have sometimes been tried without adequate premarket clinical testing, quality control in materials selected, or patient consent.[119]

The Dalkon Shield, a contraceptive device introduced in November 1970, is "an example of a legitimate device which was marketed without adequate premarket testing."[120] Other examples

[115] U.S. Congress, House Committee on Interstate and Foreign Commerce, *Medical Device Amendments of 1976*, to accompany H.R. 11124, 94th Cong., 2nd sess., February 29, 1976, H. Rept. 94-853, p. 6.

[116] Ibid. "A device is adulterated if it includes any filthy, putrid, or decomposed substance, or if it is prepared, packed, or held under unsanitary conditions. A device is misbranded if its labeling is false or misleading; unless it identifies the manufacturer, packer, or distributor and quantity of contents; if required labeling statements are not conspicuous; if it fails to bear adequate directions for use or adequate warnings; or if it is dangerous to health when used as indicated."

[117] Ibid.

[118] Ibid., p. 7.

[119] Ibid., p. 7-8.

[120] Ibid., p. 8. By 1975, the Dalkon Shield had been linked to at least 16 deaths and 25 miscarriages, numerous cases of (continued...)

include defective cardiac pacemakers and intraocular lenses which, following implantation, caused unusual eye infections resulting in serious vision impairment or the need for removal of the eye.

Congress amended the FFDCA in 1962 to require FDA approval of a new drug application prior to marketing and to require that a new drug be shown to be effective as well as safe. Following these changes, FDA began "to impose rigorous premarket approval of some products that today would be deemed devices." Court decisions in the late 1960s upheld FDA's authority to regulate some medical devices as drugs due in part to the overlapping definitions of drug and device in the 1938 law. FDA classified a number of devices as drugs (contact lenses, injectable silicone, pregnancy-test kits, bone cement), and only such devices were subject to premarket review (prior to 1976). However the approach of classifying devices as a drug was unsuccessful in other court decisions and the need for more comprehensive authority to regulate devices was recognized by the Kennedy, Johnson and Nixon administrations.[121]

The Medical Device Amendments of 1976

The *Medical Device Amendments of 1976* (MDA; P.L. 94-295) was the first major legislation passed to address the review of medical devices. The MDA provided a definition for the term device.[122] It established a number of requirements referred to as *general controls* that applied to all devices.[123] Examples include provisions on adulteration and misbranding, prohibitions on false or misleading advertising, and a requirement to register all medical device manufacturers with FDA. One such provision required manufacturers to notify FDA 90 days prior to the marketing of any new device; if the agency failed to act, marketing could begin. Because this provision is outlined in section 510(k) of the FFDCA, it is often referred to as a "510(k) notification."

The MDA directed FDA to classify, into one of three classes, all medical devices that were on the market at the time of enactment; these are the *preamendment* devices.[124] Congress provided

(...continued)

pelvic perforation and pelvic infection, removal of the IUD for medical reasons, and pregnancies due to IUD failure. As of February 1976, more than 500 lawsuits seeking compensatory and punitive damages totaling more than $400 million were pending against the manufacturer of the Dalkon Shield. IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 172, http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx.

[121] U.S. Congress, House Committee on Interstate and Foreign Commerce, *Medical Device Amendments of 1976*, to accompany H.R. 11124, 94th Cong., 2nd sess., February 29, 1976, H. Rept. 94-853, p. 8-9.

[122] An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The definition was changed in 1992 from "any of its principal intended purposes" to "its primary intended purposes." Current definition at FFDCA §201(h), (21 U.S.C. 321).

[123] The law has since been amended to exempt many (Class I) products from some general controls or to limit the application of general controls to subsets of (Class II or Class III) products that pose higher risks. IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 175.

[124] Preamendment devices were presumed to be marketable. They did not undergo premarket review and could be legally marketed unless FDA required their removal. After classifying the preamendment devices, FDA used them as (continued...)

definitions for the three classes—Class I, Class II, Class III—based on the risks to patients posed by the devices. In contrast to the approach taken with pharmaceuticals (all, except generic agents, undergo rigorous premarket review and approval), Congress limited premarket approval to only a small number of devices. "Only the highest-risk category [Class III] would require agency review and approval as a precondition for commercial sale and routine medical use. The other two categories would be subject not to a rigorous review but merely a requirement [510(k)] that the manufacturer of a device notify FDA, at least 90 days before commencing marketing, of its intent to distribute the product commercially."[125] For Class I devices, no additional review was needed once the status of Class I was confirmed; general controls were considered to be sufficient to protect public health. For Class II devices, limited supplemental review would be needed to verify conformity with performance standards if such standards had been established by the agency.[126]

Under MDA, all devices coming to market after enactment were automatically placed in Class III until reclassified; these are the *postamendment* devices. As stated above, Class III medical devices receive more intense scrutiny and require an application for premarket approval (PMA) before the device can be marketed. However, the MDA allowed for the reclassification of a device from one class to another. According to a 2011 IOM report on medical devices:

> The classification and reclassification process did not include any evaluation of the safety or effectiveness of the device types being categorized. Once a device type was assigned to Class III, the FDA was directed to promulgate a regulation calling for manufacturers of devices of that type to submit a [PMA] application. The agency would then (and only then) undertake a review of the safety and effectiveness of the devices. For device types placed into Class I or Class II, there was no mechanism for the systematic review of safety and effectiveness. Congress envisioned instead that the agency would use its postmarketing tools to identify and address issues of lack of safety or lack of effectiveness case by case. Thus, preamendment devices in Class I and II were never subjected to a comprehensive FDA evaluation for safety or effectiveness. The classification process was not completed until 1988.[127]

For postamendment devices, which were automatically placed into Class III, there were two important exceptions:

> The primary exception involved a postamendment device that was substantially equivalent to another device of the same type that either as a preamendment device that had not been classified into any class or was not a preamendment device but had already been classified into Class I or Class II. The FDA permitted manufacturers of postamendment devices to demonstrate substantial equivalence to a preamendment device in Class I or II as part of the 510(k) submission. An alternative exception provided that the postamendment device would not be in Class III if the FDA, in response to a petition, classified it into Class I or Class II.[128]

The MDA did not provide a definition for the term *substantially equivalent.* The MDA also did not itemize the required contents of a 510(k). Such a notification "need only set forth its proposed

(...continued)

the first cadre of "predicate" devices in order to demonstrate substantial equivalence.

[125] Ibid., p. 24.

[126] Ibid., p. 177.

[127] Ibid., p. 25.

[128] Ibid., p. 179.

intended use or indications for use, the device to which substantial equivalence is claimed, and evidence demonstrating that equivalence."[129]

The Safe Medical Devices Act of 1990

The *Safe Medical Devices Act of 1990* (SMDA; P.L. 101-629) made a number of changes to the law such as providing a definition for the term *substantial equivalence* and revising the definition for Class II. FDA had not promulgated performance standards for most Class II devices. The new law authorized the use of alternative restrictions, called special controls, at the agency's discretion and simplified the process of establishing performance standards for Class II devices. Examples of special controls include special labeling requirements, mandatory performance standards, patient registries and postmarket surveillance.

FDA also had experienced difficulty in promulgating regulations needed to require submission of PMA applications for Class III devices. SMDA authorized FDA to reconsider all the preamendment devices that had been placed in Class III and reclassify some of these devices into Class I or Class II.[130] The purpose was "to reduce the number of device types that needed PMA review."[131] For those devices remaining in Class III, the agency was directed to establish a schedule for promulgation of regulations calling for PMAs of devices that still used the 510(k) notification as an entry to the marketplace.

U.S. Supreme Court 1996 Opinion
Medtronic v. Lohr

"Substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the latter is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the latter device may also be risky or ineffective." Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

Under SMDA, FDA must issue a response to a 510(k) submission before marketing of a new device can begin. SMDA allowed for the evaluation of safety and effectiveness data in 510(k) notifications, but only in certain situations. These were limited to cases in which a new device offered different technologic characteristics from the already marketed *premendment or postamendment* (predicate) device.[132] "Because the assessment of substantial equivalence generally did not require evidence of safety or effectiveness of a device and because a preamendment device to which equivalence was established was not itself reviewed for safety or effectiveness, the FDA made clear from the outset that clearance of a 510(k) notification was not a determination that the cleared device was safe or effective. That position was reiterated by the agency numerous times. The US Supreme Court accepted this interpretation in a 1996 opinion."[133]

SMDA established postmarket requirements for medical devices. SMDA required facilities that use medical devices to report to FDA any incident that suggested that a medical device could

[129] Ibid. p. 180.

[130] FFDCA §515(i).

[131] IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 205.

[132] FFDCA §513(i).

[133] IOM, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Washington, DC, July 2011, p. 28.

have caused or contributed to the death, serious illness, or injury of a patient. Manufacturers of certain permanently implanted devices were required to establish methods for tracking the patients who received them and to conduct postmarket surveillance to identify adverse events. The act authorized FDA to carry out certain enforcement actions, such as device product recalls, for products that did not comply with the law.

The Food and Drug Administration Modernization Act of 1997

The *Food and Drug Administration Modernization Act of 1997* (FDAMA; P.L. 105-115) mandated wide-ranging reforms in the regulation of foods, drugs and medical devices by FDA. In general, provisions involving medical devices "were designed to reduce FDA's workload and permit concentration of resources on devices that presented greater potential for harm" and "to limit the FDA's discretion and authority in regulating the device industry" in order to "accelerate the pace of technology transfer."[134]

FDAMA eliminated the 510(k) notification requirement for most Class I devices and some Class II devices. It authorized the creation of a third-party review system of 510(k) submissions for Class I and most Class II devices that still required 510(k) review. It allowed certain new devices (those not substantially equivalent to another device and automatically placed in Class III) to be evaluated for immediate placement in Class I or Class II. This process, called the de novo 510(k), avoids PMA review, must be completed in 60 days, and may be requested by the sponsor.

For substantial equivalence determinations in which the new device has a different technological characteristic, FDAMA requires that FDA "consider the least burdensome means of demonstrating substantial equivalence and request information accordingly."[135] For a medical device using an important breakthrough technology, or which does not have an approved alternative device, priority review of the PMA must be provided by FDA.[136]

FDAMA limited the use of some postmarket controls (device tracking and postmarket surveillance) to Class II and Class III devices, eased reporting requirements of adverse events for device user facilities, eliminated mandatory reporting of adverse events by medical device distributors, and directed FDA to establish a sentinel reporting system to collect information on deaths and serious injuries or illnesses associated with the use of a medical device.[137]

User Fee Acts and the FDA Amendments Act of 2007

The *Medical Device User Fee and Modernization Act of 2002* (MDUFMA; P.L. 107-250) established a user fee program for premarket reviews of 510(k) submissions and PMA applications; user fees may not be used for other FDA or CDRH activities. MDUFMA also made targeted changes that would reduce regulatory burdens and agency workload, such as allowing establishment inspections to be conducted by accredited persons (third parties). MDUFMA was amended and clarified by two laws: the *Medical Device Technical Corrections Act of 2004*

[134] Ibid., p. 213.

[135] FFDCA §513(i)(1)(D).

[136] FFDCA §515(d)(5).

[137] FFDCA §519 and §522. A device user facility means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office.

(MDTCA, P.L. 108-214), and the *Medical Device User Fee Stabilization Act of 2005* (MDUFSA, P.L. 109-43), and had its user fee provisions reauthorized by the *Medical Device User Fee Act of 2007* (MDUFA; Title II of FDAAA, see below).

The *Food and Drug Administration Amendments Act of 2007* (FDAAA; P.L. 110-85) amended the FFDCA and the Public Health Service Act to reauthorize several expiring programs (including the medical device user fee act) and to make agency-wide changes, several of which have implications for the regulation of medical devices.[138] FDAAA created incentives as well as reporting and safety requirements for manufacturers of medical devices for children; required that certain clinical trials for medical devices and some other products be publicly registered and have their results posted;[139] created requirements to reduce conflicts of interest in advisory committees for medical devices and other products;[140] and made certain other amendments to the regulation of devices.

[138] See CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by Erin D. Williams and Susan Thaul.

[139] See the Clinical Trials Databases section of CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by Erin D. Williams and Susan Thaul.

[140] FDA uses advisory committees to gain independent advice from outside experts. See CRS Report RS22691, *FDA Advisory Committee Conflict of Interest*, by Erin D. Williams.

Appendix B. Acronyms Used in this Report

BIMO	Bioresearch Monitoring
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CSOs	Consumer safety officers
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
FFDCA	Federal Food, Drug and Cosmetic Act
GAO	General Accountability Office
GGP	Good Guidance Practices
GHTF	Global Harmonization Task Force
GMP	Good manufacturing practices
HHS	Health and Human Services
IDE	Investigational Device Exemption
IOM	Institute of Medicine
IRB	Institutional review board
IVD	In Vitro Diagnostic
MDA	Medical Device Amendments of 1976
MDR	Medical Device Reporting
MDTCA	Medical Device Technical Corrections Act of 2004
MDUFA	Medical Device User Fee Act of 2007
MDUFMA	Medical Device User Fee and Modernization Act of 2002
MDUFSA	Medical Device User Fee Stabilization Act of 2005
NSE	Not substantially equivalent
OC	Office of Compliance
ORA	Office of Regulatory Affairs
PMA	Premarket Approval
QSR	Quality Systems Regulation
SMDA	Safe Medical Devices Act of 1990
UDI	Unique device identification

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In Press PlosOne-DOI:
10.1371/journal.pone.0032037

Early versus Delayed Decompression for Traumatic Cervical Spinal Cord Injury: Results of the Surgical Timing in Acute Spinal Cord Injury Study (STASCIS)

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Key words: Spinal Cord Injury, Surgical Timing, Neurologic Outcomes, Complications

Abstract

Background:

There is convincing preclinical evidence that early decompression in the setting of spinal cord injury (SCI) improves neurologic outcomes. However, the effect of early surgical decompression in patients with acute SCI remains uncertain. Our objective was to evaluate the relative effectiveness of early (<24 hours after injury) versus late (≥24 hours after injury) decompressive surgery after traumatic cervical SCI.

Methods:

We performed a multicenter, international, prospective cohort study (Surgical Timing in Acute Spinal Cord Injury Study: STASCIS) in adults aged 16-80 with cervical SCI. Enrolment occurred between 2002 and 2009 at 6 North American centers. The primary outcome was ordinal change in ASIA Impairment Scale (AIS) grade at 6 months follow-up. Secondary outcomes included assessments of complications rates and mortality.

Findings:

A total of 313 patients with acute cervical SCI were enrolled. Of these, 182 underwent early surgery, at a mean of 14.2(±5.4) hours, with the remaining 131 having late surgery, at a mean of 48.3(±29.3) hours. Of the 222 patients with follow-up available at 6 months post injury, 19.8% of patients undergoing early surgery showed a ≥2 grade improvement in AIS compared to 8.8% in the late decompression group (OR=2.57, 95% CI:1.11,5.97). In the multivariate analysis, adjusted for preoperative neurological status and steroid administration, the odds of at least a 2 grade AIS improvement were 2.8 times higher amongst those who underwent early surgery as compared to those who underwent late surgery (OR=2.83, 95% CI:1.10,7.28). During the 30 day post injury period, there was 1 mortality in both of the surgical groups. Complications occurred in 24.2% of early surgery patients and 30.5% of late surgery patients (p=0.21).

Conclusion:

Decompression prior to 24 hours after SCI can be performed safely and is associated with improved neurologic outcome, defined as at least a 2 grade AIS improvement at 6 months follow-up.

Introduction

The prevalence of traumatic spinal cord injury (SCI) worldwide is approximately 750 per million with an annual incidence that appears to be rising[1]. Given the impact of SCI on the individual and society, it is clear that effective therapies aimed at reducing the extent of tissue destruction and improving neurologic outcomes after the initial spinal cord trauma are urgently needed. Current concepts of the pathophysiology of acute SCI indicate that there are both primary and secondary mechanisms that lead to neurologic injury[2,3,4]. The primary injury, usually caused by rapid spinal cord compression and contusion, initiates a signaling cascade of down-stream events collectively known as secondary injury. Preventing and mitigating these secondary mechanisms is where opportunity for neuroprotection lies and where most attempts at therapeutic intervention have been staged.

The balance of existing laboratory evidence supports the theory that decompressive surgery of the spinal cord after SCI attenuates secondary injury mechanisms and improves neurological outcomes[5,6,7,8,9,10,11,12,13,14,15]. Furthermore, the strength of this neuroprotective effect seems to vary inversely with the time elapsed from injury to the decompression[8,15]. This work has translated into the clinical hypothesis that those who undergo surgery in a timely fashion post injury will experience less neural tissue destruction and improved clinical outcomes as compared to injury matched patients treated conservatively or with surgery in a delayed fashion.

However, the clinical evidence compiled to date has failed to provide robust support for this hypothesis. One small randomized controlled trial and several other prospective studies showed no benefit to early decompression, with the caveat that early was defined as within 72 hours from the time of injury and that enrolment was limited to a single centre[16,17,18,19]. In contrast, a systematic review suggested that decompression within 24 hours resulted in improved outcomes compared to both delayed decompression and conservative treatment[20]. Based on the best available evidence, the Spine Trauma Study Group adopted the 24 hour cutoff to define early versus late decompressive surgery after SCI [21].

To date, there have been no published studies that have systematically examined a large cohort of patients who underwent decompression earlier than 24 hours. To address this void, we present the results of the Surgical Timing in Acute Spinal Cord Injury Study (STASCIS), a multi-center prospective cohort study that was undertaken to compare the relative effectiveness of early (less than 24 hours post injury) versus late (24 hours or greater post injury) surgery with respect to neurological outcome 6 months post cervical SCI. As secondary questions, we assessed the impact of surgical timing on in-hospital postoperative complication rates and mortality.

Methods

We have completed a prospective, multicenter, cohort study involving hospitals at 6 institutions throughout North America: 1) University of Toronto, Toronto, Ontario, Canada 2) Thomas Jefferson University, Philadelphia, PN, USA 3) University of Virginia, Charlottesville, VA, USA 4) University of Maryland, Baltimore, MD, USA 5) University of British Columbia, Vancouver, British Columbia, Canada; 6) University of Kansas, Kansas City, KS, USA. Each of the hospitals involved are specialized in the management of spinal trauma and spinal cord injury. Patient enrollment began in August 2002 and ended in September 2009. Research ethics board approval was obtained at each of the 6 centers prior to beginning enrollment. During this period any SCI patient presenting to one of these institutions was assessed for suitability against a predefined set of inclusion and exclusion criteria (Table 1).

At presentation, neurologic examination was performed as per standards established by the American Spinal Injury Association (ASIA) and injury characteristics were classified according to neurologic level of injury (NLI), ASIA motor score (AMS), ASIA sensory score (ASS) and the overall ASIA Impairment Scale (AIS) grade. The baseline ASIA assessment was performed within 24 hours on all subjects. The primary outcome measure of interest was ordinal change in AIS grade at 6-months follow-up. The 6 month time period for follow-up was based on recommendations used in the NASCIS and Sygen trials as well as on the findings of previous natural history studies which demonstrate that the vast majority of neurological recovery occurs during this period[22,23,24,25,26,27]. Additional clinical parameters collected at admission included patient age, gender, mechanism of injury, Charleson Co-morbidity Index (CCI) and initial Glasgow Coma Scale (GCS) score. Prior to study enrollment, each patient underwent a plain X-Ray, computed tomographic (CT) scan and magnetic resonance imaging (MRI) study of their cervical spine. Particular note was made of the presence of spinal cord compression on MRI as this defined one of the major study inclusion criteria. Spinal cord compression was defined by the method we have previously described[28]. For patients unable to undergo MRI, CT or CT-myelography was performed.

After initial clinical and radiographic evaluation, study eligibility was determined. After enrollment, subjects underwent either early (<24 hours after injury) or late (≥24 hours after injury) decompressive surgery of the cervical spinal cord. Decision of surgical timing was dependent on the time elapsed post injury at patients' hospital arrival, the time required to obtain diagnostic investigations, and the discretion of the attending spinal surgeon. The specifics of the surgical intervention, such as the direction of approach (anterior vs. posterior) and number of levels decompressed, were also decided based on the judgment of the attending spinal surgeon. In all cases, decompression was accompanied by an instrumented fusion procedure. Apart from the surgical management, all patients received appropriate medical support according to the 2002 American Association of Neurological Surgeons cervical SCI guidelines, which included permissive or induced hypertensive therapy (mean BP > 85 mm Hg)[29,30,31]. Methylprednisolone was used as per the discretion of the treating team according to the

recommendations of the NASCIS-2 study[25]. CT imaging was performed within 72 of surgery for all patients, and read by a site specific radiologist, to establish the patency of the spinal canal in the postoperative setting. In specific circumstances, such as postoperative neurological deterioration, repeat MRI scan was performed to evaluate the spinal cord and to exclude the presence of ongoing spinal cord compression. Lastly, all patients underwent a post-operative rehabilitation regimen, tailored to individual and injury specific factors.

When unilateral or bilateral cervical facet dislocation was diagnosed on initial X-ray or CT scan, these patients were reduced, on an emergent basis, by either closed or open means. A MRI was obtained following closed reduction to document the degree of decompression of the spinal cord achieved. If the post reduction MRI demonstrated complete resolution of spinal cord compression, then the time at which closed reduction was achieved was recorded as the time of decompression.

After surgery, patients were analyzed in groups according to the timing of their operative intervention. A trained research assistant, blinded to the timing of patients' surgical treatment, performed follow-up neurological examinations at acute hospital discharge and 6 months post-operatively. Documentation of relevant in-patient postoperative complications was also performed. For the complications analysis, patients without 6 month follow-up data were also included since complications data from the acute hospital admission were available for all patients enrolled.

Statistical Analysis

All analyses were performed using SAS 9.2. To determine the effects of surgical timing on AIS grade improvement and to account for baseline discrepancies between the cohorts, we performed a generalized ordinal logistic regression analysis. The dependent variable was ordinal change in AIS grade from pre-operative baseline to 6 months post-operatively, and the independent variable of interest was defined as surgical timing (early vs. late). Predictor variables related to baseline patient characteristics, such as age, gender, complete (AIS A) vs. incomplete (AIS B-D) neurological status at admission and steroid administration, were included in the initial model and sequentially eliminated in a backwards fashion, if their corresponding p-value was greater than 0.05. Continuous variables were compared between the treatment groups using the student t-test. Categorical data were analyzed by Fisher's exact and chi-squared tests.

Results

Study Population

A total of 470 subjects were screened for enrollment of which 313 satisfied study inclusion and exclusion criteria (Figure 1). Of the 313 study participants, 182 underwent surgery less than 24 hours after SCI and were considered the early surgery cohort. The remaining 131 patients underwent surgery at or after 24 hours post SCI and were considered the late surgery cohort. Both groups were followed prospectively over time until 6 months post injury. During the study period, 5 patients died and 86 patients were lost to follow-up, leaving a total study population of 222 on which to base the 6 month analysis. In the early surgery group, 4 patients died and 47 were lost to follow-up, leaving 131 patients. In the late surgery group 1 patient died and 39 were lost to follow-up, leaving 91 patients. Within the early surgery group the mean time to surgery was 14.2(±5.4) hours and 48.3(±29.3) hours within the late surgery group ($p<0.01$). No patient in either group underwent repeat operation for inadequate decompression as determined by postoperative imaging.

Table 2 gives a comparative breakdown of the demographic and injury characteristics of the entire study population, the early surgery group and the late surgery group. In the early surgery cohort the mean age was 45.0±17.2 with 140 males (76.9%) and 42 females (23.1%). In the late surgery cohort the mean age was 50.7±15.9 years with 96 males (73.3%) and 35 females (26.7%). There was no significant difference in the distribution of gender between the two groups, however there was a statistically significant difference in mean age between the groups, with patients in the early surgery cohort tending to be younger ($p<0.01$). The neurologic status on admission was significantly different between the cohorts with AIS grade A's and B's overrepresented in the early group and C's and D's more common in the late group ($p<0.01$). The majority of injuries in both cohorts resulted from either motor vehicle accidents or falls with no significant differences in etiology between groups.

In the entire study population 194 patients (62.0%) received steroids at hospital admission, with a significantly higher proportion of administration in the early as compared to the late group($p=0.04$).

Neurologic Recovery at 6 months

In the entire study group, the degree of neurologic improvement was significant as measured by change in AIS grade from presentation to 6 months follow-up ($p=0.02$) (Table 3a). In the early surgery group, AIS grade improvement was as follows: 56 (42.7%) had no improvement, 48 (36.6%) had a 1 grade improvement, 22 (16.8%) had a 2 grade improvement, 4 (3.1%) had a 3 grade improvement and 1 (0.8%) had a 1 grade worsening (Table 3b). In the late group, AIS grade improvement was as follows: 46 (50.6%) had no improvement, 37 (40.7%) had a 1 grade improvement, 8 (8.8%) had a 2 grade improvement, and no patient worsened (Table 3c). Based on this information, 74 patients (56.5%) in the early group and 45 patients (49.5%) in the late

group experienced at least a 1 grade improvement (*early vs. late surgery:* OR =1.33, 95% CI:0.78,2.27) and 26 patients (19.8%) in the early group and 8 patients (8.8%) in the late group experienced at least a 2 grade improvement (*early vs. late surgery:* OR=2.57, 95% CI:1.11,5.97) at 6 months (Figure 2).

In development of the multivariate regression model, after backwards elimination of predictors with p-values >0.05, in addition to surgical timing, only complete vs. incomplete status and steroid administration remained in the regression equation (Table 4). The odds of at least a 2 grade AIS improvement were 2.8 times higher amongst those who underwent early surgery as compared to those who underwent late surgery, after adjusting for preoperative neurologic status and steroid administration (OR=2.83, 95% CI:1.10,7.28). The odds of a 1 grade AIS improvement were 1.4 times higher amongst those who underwent early surgery as compared to those who underwent late surgery, after adjusting for preoperative neurologic status and steroid administration, however this was not statistically significant (OR=1.37, 95% CI:0.80,2.57).

Postoperative Complications and Mortality

Of the 313 patients who were enrolled and underwent surgery, there were a total of 97 major post-operative inpatient complications that occurred in 84 individuals. Table 5 provides a synopsis of the postoperative complications in each group. In the early group, 44 individuals (24.2%) experienced 48 complications and, in the late group, 40 individuals (30.5%) experienced 49 complications. Although there was a lower proportion of patients in the early surgical group who experienced at least one complication (24.2%) as compared to the late surgery group (30.5%), this difference was not statistically significant (p=0.21).

During the 30 day post injury period there was 1 mortality in both the early and late surgery groups. The death in the early surgery patient was secondary to a postoperative myocardial infarction and the death in the late surgery patient was related to pulmonary complications. Subsequent to the 30 day post injury time window, 3 deaths occurred in the early surgery group, all from cardio-respiratory causes, and no deaths occurred in the late surgery group.

Discussion

STASCIS represents the largest prospective multi-center study comparing early vs. late surgical decompression in the setting of acute traumatic spinal cord injury. Results of the unadjusted analysis indicate a significant difference, favoring the early group, in the proportion of patients recovering at least 2 AIS grades at 6-months follow-up. The Sygen trial, the largest therapeutic trial in SCI, defined significant neurologic recovery as at least a 2 grade AIS improvement at 6 months follow-up[22]. In applying a similar definition to the current study, the unadjusted analysis demonstrated a more favorable neurologic recovery amongst those treated with early surgery. The multivariate regression analysis, adjusted for preoperative neurological status and steroid administration, continued to demonstrate that patients who underwent early surgery were more likely to improve at least 2 AIS grades at follow-up.

Having demonstrated the potential for improved neurological outcomes with early surgical decompression, the obvious question becomes: how does one define 'early'? The notion of early surgery stems from an increased understanding of secondary mechanisms of SCI deduced primarily from animal data[32,33]. In a recent systematic review of the preclinical literature, 19 studies were identified evaluating decompression in several different animal SCI models [34]. Of these, 11 reported a time dependent effect favoring early surgery, with outcome variably defined in terms of follow-up functional status, degree of tissue destruction on post-mortem histological analysis or electrophysiological findings. In most of these animal studies, the timing of surgical decompression was in the range of 8 to 24 hours post injury, an experimental model that is difficult to replicate in clinical situations where practical factors limit this possibility. As a result, while the preclinical literature establishes a clear biologic rationale to support early decompressive surgery, it is impossible to extract from these studies an optimal therapeutic window for the surgical treatment of human SCI patients. With respect to the existing clinical evidence, a recent systematic review of the human literature concluded that decompression within 24 hours of injury resulted in improved outcomes compared to either delayed surgery (> 24 hours) or conservative treatment [20]. To elaborate, the SCI literature has been historically variable on the definition of timing. Out of 22 studies attempting to define optimal timing for surgery after acute traumatic SCI, 9 utilized the 24 hour limit to define an early decompressive operation[35,36,37,38,39,40,41,42,43], 8 used 72 hours [18,19,44,45,46,47,48,49], and 4 used other benchmarks such 8 hours, 48 hours or 4 days[50,51,52,53]. Importantly, no study has associated adverse neurologic outcomes with early surgical intervention, regardless of a specific time cutoff. Based on the biology of secondary mechanisms in spinal cord injury, the Spine Trauma Study Group [21] has operationally defined early intervention as occurring within 24 hours. Our decision to employ the 24 hour definition was based on analyzing the available preclinical and clinical data which suggested that outcomes, neurologic and otherwise, would be potentially optimized if surgery was performed between 8 and 24 hours post injury. In spite of this, all recommendations made to date have lacked the support of a large systematic comparative analysis evaluating the relative efficacy of various surgical timing cutoff points.

Comparing the rates of AIS grade conversion in the current study to those reported in other large SCI series, it is clear that we report superior rates of recovery, particularly amongst AIS grade A patients, regardless of the surgical group considered. When both cohorts are taken together, 40% of preoperative AIS grade A patients (43% in the early group and 37% in the late group) experienced at least a 1 grade improvement, compared to historical rates of 15-25%[54]. We attribute this difference to our exclusion of patients with severe concomitant injuries, use of a rigorous, standardized protocol of management including induced hypertensive therapy, and focus on a cervical cohort, where the potential for recovery is greater than for those with severe thoracic injuries.

The pivotal point of this study was to compare the relative effectiveness of early and late surgical decompression with respect to neurological outcomes for those sustaining traumatic cervical SCI. As with any methodological design, there are certain limitations that are recognized. Although a randomized trial would have been, in theory, methodologically superior to address the therapeutic efficacy of this intervention, we chose a prospective cohort design for both practical and ethical reasons. From a practical standpoint, it has been shown in previous feasibility studies that between 23.5% and 51.4% of SCI patients can undergo an operation within the first 24 hours after injury due mainly to transport and life saving measures[35,43]. If we were to perform a study randomizing patients to early versus late decompression, the study population would be based only on the one quarter to one half of the total SCI population who are eligible to undergo surgery within 24 hours of injury, introducing significant selection bias. From an ethical standpoint, there was consensus among participating surgeons that it would be unacceptable to withhold decompressive surgery to a patient deteriorating neurologically with significant concomitant spinal cord compression; highlighting the point that it is nearly impossible to achieve clinical equipoise in a trauma population, a prerequisite for a proper randomized trial.

In the current study, all patients, regardless of whether they received early or late surgery, underwent a standard ASIA neurological examination within 24 hours of injury. Results of neurological examinations performed within this period have shown to be valid and are consistent with examination results obtained at 72 hour post injury, except amongst patients with an associated traumatic brain injury[55,56]. In order to ensure that initial neurological assessments were not confounded by extraneous factors, patients with head injuries (GCS $\leq$13) and significant poly-trauma were not enrolled. Another perceived threat to the validity of the acute neurological assessment has previously been the presence of spinal shock. However, according to the most recent evidence on the topic, spinal shock likely represents an ongoing physiologic continuum consisting of 4 stages, occurring in virtually all patients with severe SCI, beginning within minutes after injury and continuing for up to 12 months[57]. Based on this modern definition, it would be inappropriate to identify an SCI patient as being “in” or “out of” spinal shock for purposes of classification within a study.

Study Limitations

The early surgery group included patients with a slightly lower mean age and contained a significantly greater proportion of patients with a more severe degree of initial injury as compared to the late group. These discrepancies may be a reflection of study surgeons tending to be more aggressive in the treatment of younger SCI patients with a more severe injury. An alternative explanation might be that younger patients generally have fewer co-morbidities and are less complicated to resuscitate enabling an expeditious path to decompression. Nonetheless, the multivariate analysis which controlled for baseline differences between the groups, confirmed that early decompression within 24 hours of acute cervical SCI was associated with improved neurologic outcomes. We also recognize that a fraction of the study population (27%) was lost to long term review, although our follow-up rates compare favorably to other major prospective studies in SCI including NASCIS I where the loss to follow-up at 6 months was 31%[24]. This is attributed to the inherent challenges of following a large group of trauma patients, many of whom reside in rural communities separated by large distances from the specialized study centers.

Conclusion

In the current study, decompressive surgery prior to 24 hours after SCI was performed safely and was associated with improved neurologic outcome defined as at least a 2 grade AIS improvement at 6 months follow-up. Of note, the results of this study appear to validate a growing consensus among spine surgeons favoring early surgical intervention for SCI[21]. However, these conclusions must be tempered given the inherent limitations of the cohort study design used in the STASCIS study. Therefore, further study is necessary to more accurately define which SCI patients benefit the most from early surgical intervention.

Financial Disclosure and competing interest statement

The authors wish to acknowledge the support of the following agencies and granting bodies who contributed to the study: Krembil Foundation; Christopher and Dana Reeve Foundation; Cervical Spine Research Society; AANS/CNS Section on Disorders of the Spine and Peripheral Nerves and the Rick Hansen Institute. The logistics of the study were supported by PhDx through an unrestricted grant to the Spine Trauma Study Group by Medtronic Inc. No funding bodies had any role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The authors have no conflicts of interest to declare.

Acknowledgements

The authors thank Yuriy Petrenko and David Poley for logistical support and Ting Ou for statistical assistance in data analysis and database management.

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Figure 1: Patient Flow

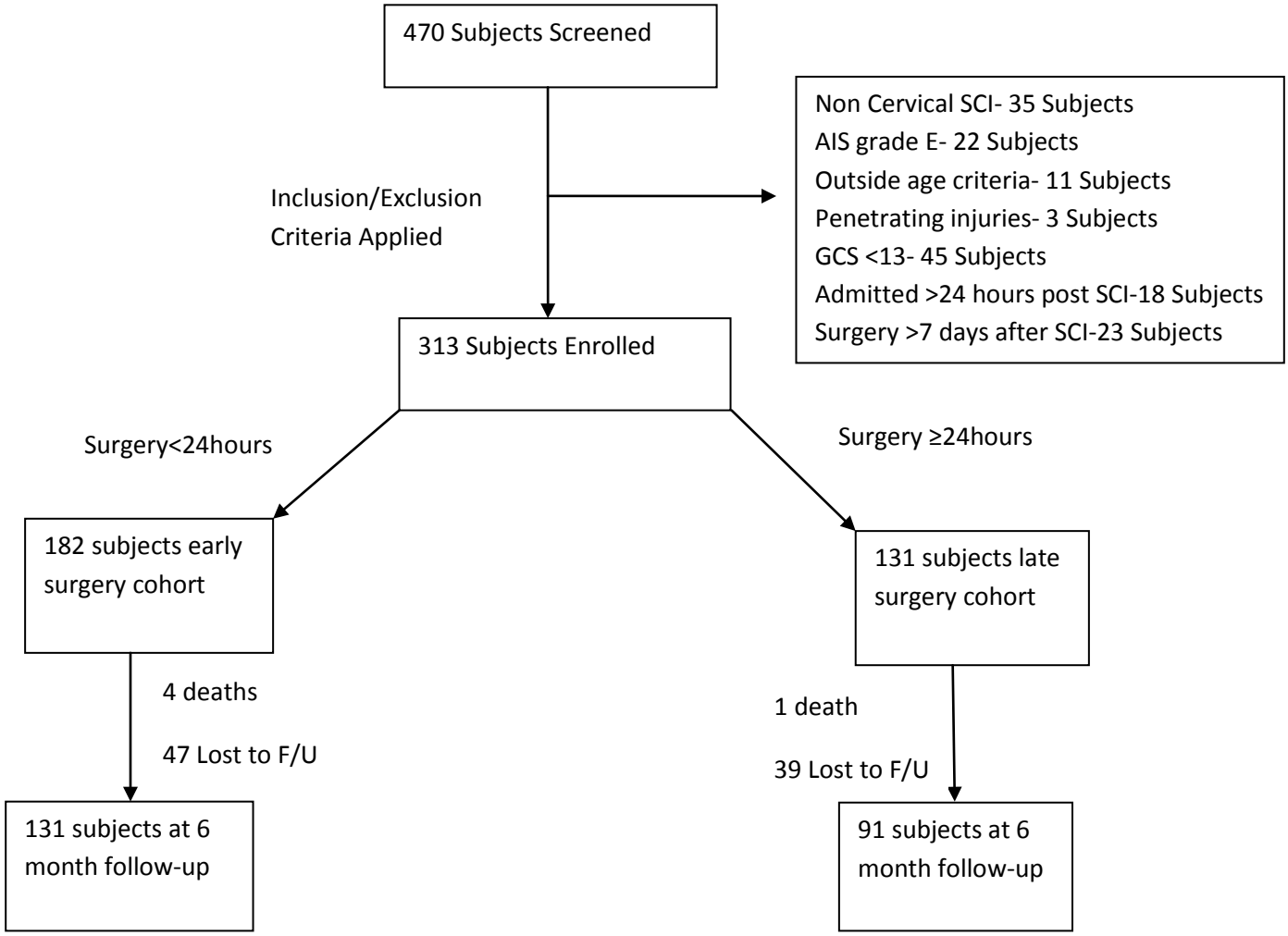

Figure 2 AIS grade Improvement at 6months: Early vs. Late Surgery

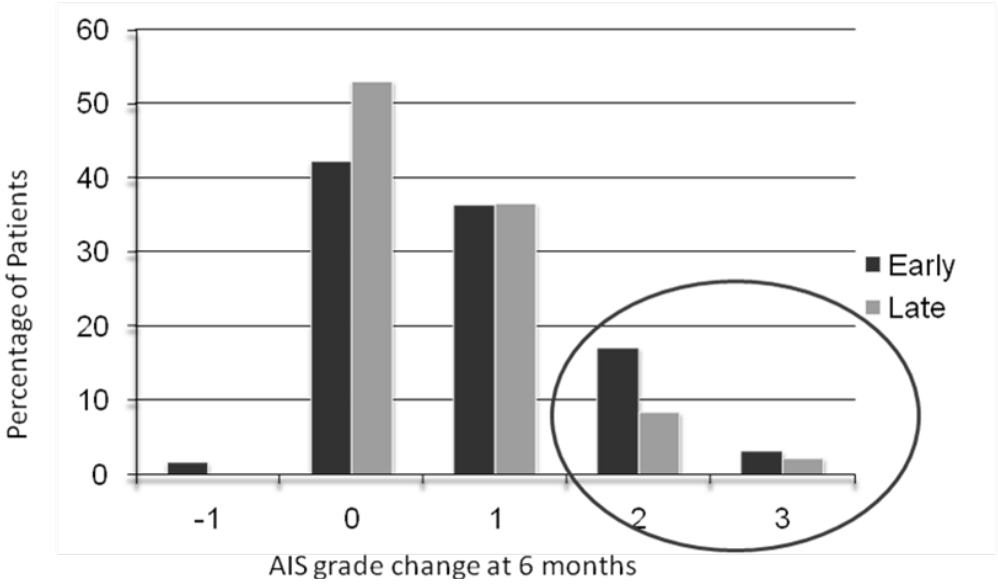

Table 1: Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1) Male or female 2) Ages 16-80 3) Initial GCS >13 4) Initial AIS grade A-D 5) Cervical spinal cord compression confirmed by MRI or CT Myelography 6) Patient or Proxy willing to provide consent for enrollment 7) Neurological Level of Injury between C2 and T1	1) Cognitive impairment preventing accurate neurologic assessment 2) Penetrating injuries to the neck 3) Pregnant females 4) Pre-injury major neurologic deficits or disease (i.e. ischemic stroke, Parkinson's Disease) 5) Life threatening injuries which prevent early decompression of the spinal cord 6) Arrival at health center > 24 hours after SCI 7) Surgery >7 days after SCI

Table 2: Patient Demographics and Injury Characteristics

characteristics	**Overall N=313**	**Early surgery N=182**	**Late Surgery N=131**	**P value**
mean age ± SD				P<0.01
	47.4±16.9	45.0±17.2	50.7±15.9	
Gender n(%)				p>0.05
Male	236 (75.4%)	140 (76.9%)	96 (73.3%)	
Female	77 (24.6%)	42 (23.1%)	35 (26.7%)	
Etiology				p>0.05
Motor Vehicle Accident	119 (38.0%)	76 (41.8%)	43 (32.8%)	
Fall	121 (38.7%)	64(35.1%)	57 (43.5%)	
assault – blunt	13 (4.2%)	8 (4.4%)	5 (3.8%)	
Sports	3 (9.6%)	16 (8.8%)	12 (9.2%)	
Other	3 (9.6%)	18 (9.9%)	14 (10.7%)	
Baseline ASIA Impairment Scale Grade				P<0.01
A	101(32.3%)	65 (35.7%)	36 (27.5%)	
B	54 (17.3%)	40 (22.0%)	14 (10.7%)	
C	66 (21.1%)	32 (17.6%)	34 (26.0%)	
D	92 (29.4%)	45 (24.7%)	47 (35.9%)	
Charleson Co-morbidity index ≥1				p>0.05
	74(23.6%)	40(22.0%)	30(26.0%)	
Glasgow Coma Scale ± SD				P>0.05
	14.9±0.4	14.9±0.4	14.9±0.4	

Table 3a Ordinal changes in AIS grade from pre-op to 6 months follow-up: Total Study Population

Preoperative AIS grade	A	B	C	D	E	Total
A	42	18	9	2	0	71
B	1	11	11	17	2	42
C	0	0	7	32	4	43
D	0	0	0	42	24	66

Table 3b Ordinal changes in AIS grade from pre-op to 6 months follow-up: Early Surgery group

Preoperative AIS grade	A	B	C	D	E	Total
A	25	11	6	2	0	44
B	1	7	9	12	2	31
C	0	0	2	16	4	22
D	0	0	0	22	12	34

Table 3c Ordinal changes in AIS grade from pre-op to 6 months follow-up: Late Surgery group

Preoperative AIS grade	A	B	C	D	E	Total
A	17	7	3	0	0	27
B	0	4	2	5	0	11
C	0	0	5	16	0	21
D	0	0	0	20	12	32

Table 4 Results of generalized ordinal logistic regression model assessing the effect of early vs. late surgical decompression, adjusted for preoperative neurological status and steroid administration.

Predictor Variable	Odds Ratio with 95% CI	p-value
Early vs. Late surgery ≥2 grade AIS improvement	2.83 (1.10,7.28)	P=0.03
Early vs. Late surgery 1 grade AIS improvement	1.38 (0.74, 2.57)	P=0.31

Table 5 Inpatient Postoperative Complications

Complication	Total Population	Early Surgery	Late Surgery
Cardiopulmonary	66 (68.0%)	32(66.7%)	34(69.4%)
Construct Failure requiring Surgery	4(4.1%)	3(6.3%)	1(2.0%)
Deep Wound Infection	2(2.1%)	0	2(4.1%)
Neurologic Deterioration	5(5.2%)	4(8.3%)	1(2.0%)
Pulmonary Embolism	4(4.1%)	2(4.2%)	2(4.1%)
Systemic Infection	14(14.4%)	6(12.5%)	8(16.3%)
Wound Dehiscence	1(1.0%)	1(2.1%)	1(2.0%)
Totals	97	48	49

Washington Update

AANS/CNS Joint Spine Section

Congress Passes Bill Preventing Medicare Pay Cut

On Feb. 17, 2012, Congress passed the Middle Class Tax Relieve and Job Creation Act, legislation that prevents the pending 27.4 percent Medicare physician pay cut, and instead freezes payment rates at their current for the remainder of the year. The House approved the measure by a vote of 293-132 and the Senate followed suit the same day with a 60-36 vote . On Feb. 22, 2012, President Obama signed the measure into law. The law also requires the Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) to submit reports to Congress regarding the development of a long-term alternative to the current Medicare physician payment system. Physicians now face an estimated 32 percent Medicare pay cut on Jan. 1, 2013 unless Congress intervenes yet again later this year. The AANS and CNS continue to press Congress to permanently repeal the flawed sustainable growth rate (SGR) system.

IPAB Repeal Markup Scheduled in House

The House Energy and Commerce health subcommittee is scheduled to mark-up legislation to repeal the Independent Payment Advisory Board (IPAB) on Feb. 28, 2012. The bill, sponsored by Rep. Phil Roe (R-TN), has 224 co-sponsors, including 16 Democrats. IPAB is a 15 member government board whose sole job is to cut Medicare spending. On Feb. 24, 2012, the IPAB coalition, organized by the AANS and CNS and representing over 350,000 physicians across 23 specialty physician groups, sent a reminder letter to the committee citing how important it was to repeal the IPAB. Our letter stated, "With the advent of the IPAB…the people's elected representatives will no longer have power over Medicare payment policy. Instead, these major health policy decisions will rest in the hands of 15 unelected and largely unaccountable individuals — or even worse. If IPAB fails to report recommendations or never becomes operational, this power will rest solely in the hands of a single individual — the secretary of the Department of Health and Human Services."

Error in CPT 2012 for New Bundled Lumbar Fusion Codes

Two new CPT codes, CPT codes 22633 and 22634, have been created effective January 1, 2012 to report lumbar arthrodesis using a combined posterior or posterolateral technique with a posterior interbody technique including laminectomy and, or discectomy sufficient to prepare interspace (other than for decompression) for each interspace and segment. Bone grafting codes 20930-20938 and spinal instrumentation codes 22840 – 22851 are separately reportable when performed with arthrodesis procedures; however, CPT inadvertently omitted the new codes 22633 and 22634 from the parenthetical notes for the graft and instrumentation codes. This omission has caused some payors to inappropriately deny payment for the codes.

AANS and CNS CPT Advisors Patrick Jacob, MD, and Joseph Cheng, MD, have joined advisors from other specialty societies in taking action to correct this error. The AMA will post a correction on the CPT website and publish a CPT Assistant article. Neurosurgeons who are denied payment for the graft and instrumentation codes used with the new bundled codes, should flag the claims and resubmit when the CPT clarification have been published.

Coverage Policies and Comparative Effective Research

- ***Spine Fusion Surgery Questioned.*** Medicare, other third party payers and health policy researchers continue to question the efficacy of lumbar spine fusion surgery. The AANS and CNS continue to review, and provide comments on, proposed coverage policies, comparative effectiveness reviews and technology assessments. During the week of Feb. 20, our excellent team developed two responses. One is a letter to First Coast, Inc., a Florida Medicare carrier, which issued a coverage policy last October. Several Florida neurosurgeons, including Pat Jacob, MD, chair of the AANS/CNS Coding and Reimbursement Committee, and Troy Tippett, MD, past president of the AANS, will be meeting with First Coast officials this week proposing additional refinements to the existing policy. This coverage policy is important as it is the first Medicare carrier to enter into this debate and will surely set the tone for others to follow. Additionally, these coverage policies are likely to serve as the post-payment (and in the case of hospitals pre-payment) review criteria in this and other states.

  Our second effort is also very important. It involves a comparative effectiveness research review of spine fusion for lumbar degenerative disc disease. While the AHRQ review is not a payer coverage policy, it will likely serve as authoritative guidance on this topic and will be used by third party payers nationwide. The team of volunteer neurosurgeons who put this comprehensive document together did a stellar job. Kudos to: Peter Angevine, MD, Joe Cheng, MD, Kurt Eichholz, MD, Kai-Ming Fu, MD, Kojo Hamilton, MD, Dan Hoh, MD, Mike Kaiser, Jack Knightly, Matt McGirt, MD, Praveen Mummaneni, MD, David Okonkwo, MD, John Ratliff, MD, Dan Resnick, MD, Tim Ryken, MD, Charley Sansur, MD, Dan Sciubba, MD, Mike Steinmetz, MD, Karin Swartz, MD, and Luis Tumialan, MD.

- ***Wellpoint Annulus Closure after Discectomy.*** Wellpoint requested input on a proposed policy for Annulus Closure after Discectomy. Joseph Cheng, MD informed Wellpoint that based on current definitions for tools, the "investigational and medically necessary" label may not be applicable. For example, if a surgeon chooses to use a new cautery system like the Aquamantys to stop bleeding instead of a "standard" Malis bipolar cautery, it does not change the "medical necessity" of the index procedure in which it is used (and is not separately billable). And as annulus closure is not separately reportable by CPT, and currently considered an incidental component of the discectomy, additional physician reimbursement for a new cautery system would not likely be separately reimbursable. If the new technology represented significant additional physician work, the issue would be less one of policy and more one of coding. Wellpoint staff was not able to answer Dr. Cheng's question but suggested a conference call with Wellpoint CMDs. Washington Office Staff has indicated to Wellpoint that a conference call would be helpful and will follow up on scheduling the call.

- ***Washington State Health Care Authority BMP Review.*** On January 30, 2012, the AANS and CNS submitted comments to the Washington State Health Care Authority regarding their recently released Technology Assessment on the use of BMP in spine fusion. Details are available at: http://www.hta.hca.wa.gov/bmp.html Joseph Cheng, MD, and John Ratliff, MD, led the Spine Section Rapid Response Team to prepared the letter, which answered questions considered key by the group in their assessment of coverage and policy. Brian Hoh, MD, Charley Sansur, MD, Kojo Hamilton, MD, Karin Swartz, MD, Lou Tumialan, MD, Pete Angevine, MD, Kai-Ming Fu, MD, Kurt Eichholz, MD and others also contributed.

- ***Noridian Post List of Possible Future LCD Topics.*** The Medicare Administrative Contractor Noridian has published a list of possible topics for a future local coverage determination (LCD) and epidural steroids and lumbar fusion are included on the list. There is no action pending currently but Noridian has said that items on the list have been identified by their carrier medical directors (CMDs) as "problematic coverage areas" that may require clarification and other education, and possibly an LCD. The CMDs are analyzing the issues to help determine whether an LCD would be warranted and cost effective. http://bit.ly/zPXAtN.

National Neurosurgery Quality and Outcomes Database (N^2QOD)

The NeuroPoint Alliance (NPA) recently launched a pilot that will serve as a foundation for a broader National Neurosurgery Quality and Outcomes Database (N^2QOD). The primary aim of this pilot is to demonstrate the feasibility of nationwide aggregate data collection through a registry with a high degree of validity and quality control. The pilot will initially focus on degenerative lumbar spine disease, but the goal is to expand the number and type of neurosurgical procedures/diagnoses over time. More specifically, the registry will aim to:

1) Establish risk-adjusted expected morbidity and outcomes for the most common surgical procedures performed by neurosurgeons. This would generate national benchmarks for 30-day morbidity, mortality, and 3 and 12-month quality outcomes that are uniquely specific for individualized patient populations and practice settings;
2) Provide practice groups and hospitals immediate infrastructure for analyzing their 30-day morbidity and mortality and 3 and 12-month outcomes in real-time, allowing timely measurement and evaluation of health-services initiatives or practice paradigm shifts;
3) Generate practice-specific quality, efficacy, and efficiency data to support claims made to private payers;
4) Generate nationwide quality, efficacy, and efficiency data to support claims made to CMS and Medicare; and
5) Demonstrate the comparative effectiveness of neurosurgical procedures.

The N^2QOD effort is being driven by an ad hoc Scientific Committee, which recently developed a set of initial data modules for the pilot, an Operations Committee, and a Business Committee. NPA has also contracted with the Vanderbilt Institute for Medicine and Public Health (VIMPH) to provide an online data-entry system and to perform back-end statistical analyses of the data and provide individualized feedback reports to practices. Recently, beta-testing began with over 20 sites participating. The annual cost is expected to be about $12,000 per center. The initial centers contributing to the pilot will remain major stakeholders in the registry's further development and their annual costs will likely be discounted in future years as the registry opens for nationwide involvement.

Representatives from and the Washington Office are working with the Office for Human Research Protections (OHRP) and the Office of Civil Rights (OCR) to address certain barriers related to informed consent.

GAO Issues Report on Implant Price Transparency

In January 2012, the Government Accountability Office (GAO) issued a new report regarding the lack of price transparency for implants. There are several references to spine implants, and it is noted that aside from organizations such as Kaiser, there are no registries tracking postoperative outcomes for devices. The report also notes:

> From 2004 through 2009, orthopedic procedures accounted for most of the growth in Medicare IMD-related expenditures. Medicare expenditures for orthopedic IMD procedures increased from $6.1 billion to $9.0 billion, an increase of 8.1 percent per year. Procedures related to knees, hips, shoulders, and the spine accounted for nearly all of Medicare's orthopedic IMD expenditures in 2009. The average growth rate of expenditures related to each of these procedure types exceeded that of non-IMD hospital procedures. Medicare expenditure growth rates for orthopedic IMD procedures exceeded that of non-IMD hospital procedures throughout our period of study. Spinal fusion procedures had the highest growth in per beneficiary expenditures—more than doubling during the period (see fig. 3).

Spine Guidelines Projects

- ***Cervical Spine Trauma Guideline.*** Mark Hadley and Bev Walters recently led an effort to update this guideline, which was originally written in 2003. At its October 2011 meeting, the JGC assigned a subgroup—Cozzens, Holly, Julien, O'Toole, Prall, Raksin, Zacko-- to review this document, with Resnick

volunteering to take the lead. This 21 chapter document was distributed to the subgroup for review in December 2011. Given interest in expediting the publication of this guideline while also respecting the JGC review process, the subgroup is serving not only as JGC members reviewing the document for methodology and content, but also as ad hoc reviewers for *Neurosurgery* in order to avoid a double review. The subgroup met via conference call to discuss its findings in early February and JGC staff is compiling the group's comments for further distribution and consideration.

- ***Lumbar Fusion Guideline.*** This document, which is about 5 years old, will soon be updated under the leadership of Mike Kaiser. The project has been stalled for various reasons. The most recent challenge was over whether to rely on NASS's 5-tiered system for grading the evidence, versus the JGC's adopted 3 tier scale. A draft of this document was expected to be available for JGC review by fall 2011. Since it is not yet ready, the authors may want to rely on the new CNS staff person, Laura Raymond, to speed it along.

- ***Thoraco-Lumbar Trauma Guideline.*** At its September 2007, the JGC identified Thoraco-Lumbar Trauma guidelines as a future priority. The Spine Section has decided to fund this project and work in collaboration with the Trauma Section. Mike Kaiser is leading this effort and will once again contract with Linda O'Dwyer (librarian from Northwestern's Galter Health Sciences Library) to update the previous literature searches. Up until recently, this project has stalled due to competing priorities. A draft of this document was expected for JGC review by the end of 2011.

Sunshine Act Proposed Regulations Released

On December19, 2011, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule entitled *Transparency Reports and Reporting of Physician Ownership or Investment Interests*, which would implement provisions of the Physician Payment Sunshine Act, including as part of the Patient Protection and Affordable Care Act (PPACA). PPACA provides that beginning in 2012, manufacturers of a drug, device, biological or medical supplies participating in U.S. federal health care programs must begin tracking any transfers of value or payments exceeding $10 to physicians and/or teaching hospitals. These reports must be submitted to the Secretary of Health and Human Services (HHS) on an annual basis. The majority of the information contained in the reports will be available on a public, searchable website in 2013, when the transfers of value cumulatively exceed $100

American Society for Testing and Materials

The American Society for Testing and Materials (ASTM) F04 Committee on Medical and Surgical Materials and Devices has created a subcommittee to review testing standards for intervertebral body fusion devices with integrated fixation components. Jean Coumans, MD has been appointed by the AANS/CNS Spine Section to follow ASTM F04 issues and attended a meeting of the F04 Committee in November. More information on the new standard being developed is available at: http://bit.ly/zTppoI. General information on the ASTM F04 Committee is available at: http://bit.ly/wqlJri.

Entering the Blogosphere and Twitter

In the coming months, the AANS/CNS Washington Office will be launching a new/social media program. One of the key elements will be a new blog entitled: **Neurosurgery Blog: More than Just Brain Surgery** (www.neurosurgeryblog.org). Additionally, we will actively follow other organizations' experiences with new communications tools with the use of Twitter to send quick news blasts to our audiences. Our Twitter handle is **@neurosurgery**. We are hoping to reach key audiences in the health policy, legislative, and media worlds (and even the public) with these new communications platforms to discuss health policies as they relate to organized neurosurgery and to bring greater attention to the achievements of AANS and CNS. We look forward to connecting with you online and we welcome your content ideas and contributions.

For More Information: Katie Orrico, Director, AANS/CNS Washington Office
Phone: 202-446-2024; Email: korrico@neurosurgery.org

February 24, 2012

The Honorable Joe Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

On behalf of the undersigned medical organizations, representing over 350,000 physicians and the patients they serve, we urge you to favorably report H.R. 452, the Medicare Decisions Accountability Act, out of committee when you mark-up the bill next week. Created by the Patient Protection and Affordable Care Act (PPACA), the IPAB is a government board whose sole job is to cut Medicare spending, and H.R. 452 would repeal this section of PPACA.

From the beginning of Medicare, Members of Congress have played an essential role in shaping policies that best meet the needs of their communities and constituents to ensure that the health care system is equipped to care for diverse populations across the country. With the advent of the IPAB, however, the people's elected representatives will no longer have power over Medicare payment policy. Instead, these major health policy decisions will rest in the hands of 15 unelected and largely unaccountable individuals. Even worse, if IPAB fails to report recommendations or never becomes operational, this power will rest solely in the hands of a single individual - the Secretary of the Department of Health and Human Services. Additionally, fewer than half of the IPAB members can be health care providers, and none are permitted to be practicing physicians or be otherwise employed. Thus, not only does the creation of IPAB severely limit congressional authority, it essentially eliminates the transparency of hearings, debate and a meaningful opportunity for critical stakeholder input.

America's physicians are also concerned that the strict budgetary targets and other limitations imposed on the IPAB will ultimately threaten the ability of our nation's seniors and disabled to obtain the health care they need, when they need it. The IPAB will be required to recommend cuts based on unrealistic spending targets starting in 2014. Unfortunately, we have all witnessed the inaccuracies associated with projecting future Medicare expenditures, most notably the problems with the sustainable growth rate (SGR) formula. It is estimated that it will now cost over $300 billion to "fix" the SGR, and we clearly cannot afford the IPAB to become the next SGR. Today, the price tag for repealing the IPAB is relatively small, so Congress should seize this moment and repeal the IPAB now before the cost to do so becomes prohibitive and access to care problems become acute. And because IPAB funding was authorized to begin on October 1, 2011 and board members can now be appointed, there is urgency for repeal before this board is established.

Finally, providers representing roughly 37 percent of all Medicare payments -- including hospitals and hospice care -- are exempt from IPAB cuts until 2020; thus IPAB directed cuts will disproportionately fall on physicians. Physicians are already facing cuts in excess of 40 percent

over the next decade, and without a permanent solution to the Medicare's sustainable growth rate (SGR) formula they could be subject to "double jeopardy" from cuts from the combined application of SGR and IPAB.

While we recognize the need to reduce the federal budget deficit and control the growth of health care spending, the IPAB is simply the wrong solution for addressing these budgetary challenges. We need a workable alternative that adequately reimburses physicians and ensures that patients will have timely access to quality care.

Leaving Medicare payment decisions in the hands of an unelected, unaccountable body with minimal congressional oversight will negatively affect timely access to quality health care for our country's senior citizens and the disabled. Hundreds of Democrat and Republican Members of Congress and organizations representing seniors, veterans, consumers, patients, healthcare providers, business and others are all calling for the repeal of IPAB. Please join them and vote to repeal the IPAB.

Thank you for considering our request.

Sincerely,

Alliance of Specialty Medicine
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Otolaryngology – Head and Neck Surgery
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Emergency Physicians
American College of Mohs Surgeons
American College of Radiology
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Society of Anesthesiologists
American Society of Breast Surgeons
American Society of Cataract and Refractive Surgery
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association
Cardiology Advocacy Alliance
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Heart Rhythm Society
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Gynecologic Oncology

cc: Members, House Energy and Commerce Committee

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President
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Milwaukee, Wisconsin

February 20, 2012

James J. Corcoran, MD, MPH
Medicare Contractor Medical Director - A/B MAC J9
First Coast Service Options, Inc.
PO Box 45274, Jacksonville, FL 32232
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Subject: Local Coverage Decision (LCD) for Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions (DL32074) Reconsideration

Dear Dr. Corcoran,

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on the proposed revision of the Local Coverage Decision for lumbar spine fusions. We appreciate, and are in agreement with, many of the substantive changes that have been made prior to implementation of the LCD, but feel that there are several additional areas on which we would like to comment.

1) Lumbar fusion following prior spinal surgery

Current wording:

- Recurrent disc herniation despite clinically appropriate postoperative nonsurgical medical management (post-operative case specific conservative therapy is prescribed as clinically appropriate in addition to documentation of pain and functional impairment).
- Adjacent segment degeneration despite clinically appropriate post-operative nonsurgical medical management (post-operative case specific conservative therapy is prescribed as clinically appropriate in addition to documentation of pain and functional impairment).
- Associated spondylolisthesis (i.e., anterolisthesis) after prior spinal surgery with ALL the following as clinically appropriate:
- Recurrent symptoms consistent with neurological compromise
- Significant functional impairment
- Neural compression is documented by recent post-operative imaging
- Unsuccessful improvement despite 3 months of clinically appropriate post-operative nonsurgical medical management (post-operative case specific conservative therapy is prescribed as clinically appropriate in addition to documentation of pain and functional impairment)
- Instability is documented by appropriate imaging
- Patient had some relief of pain symptoms following prior spinal surgery

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AANS/CNS Comment:

The AANS and CNS believe that there needs to be a recognized exclusion for those patients who present with an objective neurologic deficit, which would pre-empt the requirement for 3 months of non-operative therapy. The requirement for non-operative therapy in patients with an acute neurologic deficit in the setting of prior spinal surgery (e.g. acute motor or sensory deficit, cauda equina syndrome) is medically inappropriate. Although these acute deficits are most commonly due to neural compression and not spinal instability, spinal fusion may be considered appropriate under certain conditions in the setting of revision surgery. The typical patient with recurrent disc herniation or adjacent segment disease could require both a decompression and fusion procedure because of the iatrogenic changes to the supporting structures of the spine. If it is needed, the fusion and the decompression are best done at the same surgical time, rather that exposing the patient to the need for multiple surgical procedures for the same problem, which would increase cost and risk.

Suggested Change:

- Appropriate non-operative therapy and symptom management, as listed below, should be undertaken, in the absence of new or worsening neurologic function (e.g. Motor deficit, cauda equina syndrome).

2) Treatment of Pseudoarthrosis

Current Wording:

Treatment of pseudoarthrosis (i.e., nonunion of prior fusion) at the same level after 12 months from prior surgery and ALL of the following are met:

- Imaging studies confirm evidence of pseudoarthrosis (e.g., radiographs, CT)
- Unsuccessful improvement despite 3 months of clinically appropriate post-operative nonsurgical medical management (post-operative case specific conservative therapy is prescribed as clinically appropriate in addition to documentation of pain and functional impairment).
- Patient had some relief of pain symptoms following the prior spinal surgery
- Patient is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to any planned surgery, or has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation if accepted.

AANS/CNS Comment:

The AANS and CNS believe that this is a complex issue, and the treatment of pseudoarthrosis differs greatly among patients. We feel strongly that the presence of new or progressive deficits should exempt the requirement for non-operative therapy. Additionally, when there is radiographic evidence of symptomatic instrumentation failure (e.g. screw or rod breakage or loosening), it is medically inappropriate to subject those patients to non-operative therapy (e.g. Physiotherapy) since these measures could easily lead to further worsening.

Suggested Change:

Treatment of pseudoarthrosis (i.e., nonunion of prior fusion) at the same level after 12 months

from prior surgery and ALL of the following are met, unless there is radiographic evidence of failed instrumentation (e.g. Loosening or breakage) or new/progressive neurologic deficit:

- Imaging studies confirm evidence of pseudoarthrosis (e.g., radiographs, CT)
- Unsuccessful improvement despite 3 months of clinically appropriate post-operative nonsurgical medical management (post-operative case specific conservative therapy is prescribed as clinically appropriate in addition to documentation of pain and functional impairment).
- Patient had some relief of pain symptoms following the prior spinal surgery
- Patient is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to any planned surgery, or has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation if accepted.

3) Multi-level Fusions

Current Wording:

Limitations:

Lumbar spinal fusion for the following conditions is not considered medically necessary and is noncovered:

- When performed with initial primary laminectomy/discectomy for nerve root decompression or spinal stenosis, without documented spondylolisthesis or documentation of instability (e.g., documented intraoperative iatrogenic instability)
- Lumbar fusion at multi-levels (2 or more) for pure DDD unless case specific indications for two level or the rare three or more level planned fusion procedure is directly addressed in the pre-procedure record

AANS/CNS Comment:

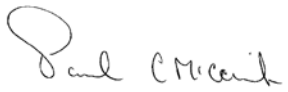
The AANS and CNS believe that this text regarding multilevel fusion is overly vague and offers little guidance to the practitioner as to how document the clinical indications for the planned procedure when felt medically appropriate. While we recognize the multilevel fusion should be performed only after careful clinical consideration, thorough evaluation and extensive efforts at non-operative resolution of the pain, the ultimate decision making is very complex. When reviewing surgical plans, it must be remembered that preoperative imaging does not uniquely identify the location for the cause of pain, and in order to afford the best possible outcome for the patient, the surgical plan must incorporate the most likely pain generators, realizing that the surgeon's judgment and experience are critical in making that determination. Thus, when medically necessary and appropriately performed, the language supporting the patient care episode should be well defined.

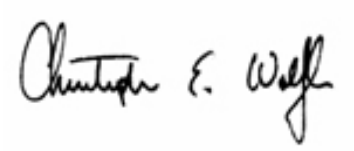
Suggested Change:

Lumbar fusion at multi-levels (2 or more) for pure DDD unless case specific indications for two level or the rare three or more level planned fusion procedure is directly addressed in the pre-procedure record (e.g. presence of degenerative deformity, anterior or lateral listhesis, severe facet arthrosis, degenerative instability on dynamic imaging, advanced degenerative end-plate changes).

Dr. Corcoran, we appreciate the opportunity to provide further input on this important topic and the refinement of the LCD. This is an area of great interest to Neurosurgeons and our patients and our organizations remain committed to providing high quality and cost effective care to our patients. Neurosurgeons representing the AANS, CNS, Florida Medical Association and the Florida Neurosurgical Society look forward to our meeting with you this week to continue this discussion. Thank you again for your consideration in this matter,

Sincerely,





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February 21, 2012

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Mail code: BICC
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Portland, Oregon 97239-3098

RE: Key Questions -- Spinal Fusion for Painful Lumbar Degenerative Disc or Joint Disease

To whom it concerns:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we would like to thank the Agency for Healthcare Research and Quality (AHRQ) for the opportunity to comment on the Key Questions regarding proposed research on the topic of "***Spinal Fusion for Painful Lumbar Degenerative Disc or Joint Disease***". We appreciate the efforts of AHRQ's Effective Health Care Program, and the research summaries regarding the benefits and risks of different treatment options for health conditions based on comparative effectiveness reviews. We also understand that these research summaries are not clinical recommendations or guidelines, but are nevertheless frequently utilized as such with respect to healthcare policy development.

For the formulation of each of these Key Questions, AHRQ has requested a description of the included studies including patient indications, methods of diagnosis, inclusion and exclusion criteria, treatments, and surgical techniques and devices used. The AANS and CNS, along with other medical societies, have developed clinical guidelines on this topic and do not feel that another systematic review of these questions will yield useful information where our previous efforts have concluded that there is a paucity of sufficient data and that the quality of the studies is limited. However, as evidenced by the similar limitations in other medical and surgical topics, this does not diminish the benefit of this surgical treatment to our patients. Questions posed for the "Comment on Key Questions" may not be clinically relevant, which may be the genesis for the state of our current medical literature, and why future studies based on these Key Questions may not lead to improvements in patient care.

With these preliminary comments in mind, we will now turn our attention to commenting on the specific questions posed by AHRQ:

1. **For adults with low back pain attributed to degenerative disc disease of the lumbar spine, does spinal fusion differ from nonoperative treatment in the ability to improve:**
   a. **Patient-centered outcomes such as function, quality of life, or pain?**
   b. **Adverse events?**

AHRQ has proposed performing a systematic review of the comparative effectiveness and safety of lumbar fusion versus nonsurgical treatment for low back pain attributed to degenerative disc disease.

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Currently, the primary treatment for most individuals with low back pain related to lumbar degenerative disease is non-operative therapy. As written, the question reflects a misunderstanding of the issue in that the population of patients treated with surgery is selected from those who have already failed extensive non-operative management. Viewing surgical and nonsurgical therapies as competing is inappropriate in this patient population as they are complementary, and surgery is typically not performed unless non-operative modalities have already failed. In this patient population, non-operative treatments have already been demonstrated to not improve outcomes.

In patients with chronic disabling pain refractory to conservative measures, lumbar fusion surgery is a potential therapeutic option. In this difficult patient population, prospective studies demonstrate a 36.0 - 63.9 percent reduction in back disability as measured by the Oswestry Disability Index (ODI) at 2 years after lumbar fusion (1, 2, 3, 4). Back pain scores also decrease 31.9 - 54.6 percent over the same duration (2, 3, 4). Further, lumbar fusion is associated with a 130.9 – 140.6 percent improvement in overall health as measured by the physical health component of the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) (1).

To date, there are four multicenter randomized controlled trials comparing lumbar fusion surgery versus nonoperative treatment for low back pain attributed to degenerative disc disease. All four studies employed standardized patient-centered outcome measures to assess function and pain. The Swedish Lumbar Spine Study Group randomized patients who failed conservative therapy for ≥ 2 years to lumbar fusion surgery versus nonoperative therapy (ranging from physical therapy, education, transcutaneous electrical nerve stimulation, epidural steroid injections, cognitive and functional training, and/ or coping strategies) (5). Patients were evaluated for 2 years post treatment. The surgical group demonstrated a 33 percent reduction in back pain score and a 25 percent decrease in ODI. Sixty-three percent of surgical patients rated themselves as “much better” postoperatively, and 36 percent had returned to work. Comparatively, the nonsurgical group demonstrated only a 7 percent reduction in back pain score and a 6 percent decrease in ODI. Only 29 percent of nonsurgical patients rated themselves as “much better” after treatment, and only 13 percent had returned to work.

Brox et al randomized a much smaller group of patients with low back pain who had failed 1 year of conservative therapy to lumbar fusion versus a nonsurgical treatment protocol consisting of a lengthy inpatient program of physical therapy, cognitive intervention, education and peer counseling which is not available in North America (6). Patients were evaluated for 1 year post treatment. The surgical group demonstrated a 36.6 percent reduction in back pain score and a 37.1 percent decrease in ODI. Conversely, the nonoperative group demonstrated only a 24.0 percent reduction in back pain score and a 30.9 percent decrease in ODI. Overall, 71 percent of surgical patients rated their treatment as successful compared to 63 percent of nonoperative patients. In a similar study, Brox et al randomized patients with low back pain after prior disc herniation surgery to either of the same treatment arms (7). More modest improvements were observed overall with the lumbar fusion group demonstrating a 21.5 percent reduction in back pain score and an 18.9 percent decrease in ODI. The nonsurgical group demonstrated a 23.5 percent reduction in back pain and a 28.4% decrease in ODI.

Fairbank et al randomized patients with degenerative disc disease related low back pain to lumbar fusion surgery versus nonoperative therapy consisting of an intensive inpatient rehabilitation program of cognitive behavioral therapy and exercise (8). Patients were evaluated for 2 years post treatment. The study was plagued by a high rate of crossover and significant patient loss to follow-up which heavily biased the study against surgical intervention given the intent to treat study design. Another significant methodological flaw related to the surgical group. Many patients were treated without fusion, making any statements regarding the efficacy of fusion based on the data from this study highly suspect. Despite the inherent biases against surgical intervention, the surgical group demonstrated a 26.9 percent decrease in ODI compared to only a 19.4 percent decrease observed in the nonoperative group. Overall general

health was assessed via the physical component of the SF-36, with the surgical group demonstrating a 148.5 percent improvement compared to only a 138.0 percent increase seen in the nonoperative group. A recent paper reported the 6-year follow-up of an FDA Phase IV study, combining patients from sites of two previous FDA trials on anterior lumbar interbody fusion for patients with DDD unresponsive to conservative care. This study reported a substantial improvement in patient daily functioning, with improvements in back pain, leg pain, Oswestry disability index (ODI), and Short-form 36 (SF-36) measures (25).

Lumbar fusion surgery for low back pain however carries risk of potential adverse events. Depending on the series, incidences of major and minor complications widely vary. Complications including neurologic events, approach related vascular injuries, wound infection, deep venous thrombosis, pseudoarthrosis, dural tear, and bone graft donor site pain among others ranged from 7.9- 46.4 percent (1, 3, 5, 6, 7, 8). Reoperation rates also widely varied ranging from 7.8 - 37.4 percent (1, 2, 3, 5, 8). Mortality after lumbar fusion surgery in these series was 0 - 0.7 percent (1, 2, 3, 4, 5, 6, 7, 8).

The existing literature demonstrates that both nonsurgical treatment and lumbar fusion surgery may improve function and pain for individuals with low back pain attributed to degenerative disc disease. While limited evidence suggests that lumbar fusion may result in better outcomes compared to nonoperative treatment for certain individuals, several systematic reviews have debated these conclusions (9, 10, 11). In 2005, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons performed a joint systematic review and concluded that there is Class I evidence to support lumbar fusion for carefully selected patients with low back pain intractable to the best medical management (12). They also found that Class III medical evidence suggests that nonsurgical treatment consisting of intensive cognitive and physical therapy may be an efficacious option for patients with chronic disabling low back pain. Given these current systematic reviews, it is unlikely that the AHRQ's proposed re-assessment of the present literature will provide any further clarification of the comparative effectiveness of surgical and nonsurgical treatment of low back pain attributed to lumbar degenerative disc disease.

2. For adults with low back pain attributed to degenerative (not congenital) stenosis of the lumbar spine, does spinal fusion differ from nonoperative treatment in the ability to improve:
   a. Patient-centered outcomes such as function, quality of life, or pain?
   b. Adverse events?

Fusion is not recommended in patients operated upon for spinal stenosis in the absence of deformity (such as spondylolisthesis, scoliosis, or regional kyphosis) or instability (pre-existing or iatrogenic) (12). There is substantial evidence indicating that surgical intervention improves pain, function, and quality of life (44). There is further evidence that these improvements are durable and cost effective. The use of fusion in this population should be applied selectively to those patients with the above listed risk factors for progressive instability or deformity. There are no non-operative measures demonstrated to improve long term outcomes in patients with neurogenic claudication due to lumbar stenosis (57, 58).

The population of patients with low back covers rather extensive subgroups and diagnoses. As such, these patients are so heterogeneous that comparison of patient-centered outcomes (such as function, quality of life, adverse events, or pain) following spinal fusion versus non-operative management is an impractical task. Several primary and secondary confounding issues, such as return to work, disability requirements, perception bias of type of treatment and also long term and short term goals of the patient, clinical practitioner and medical payer, further cloud the evaluation of effectiveness of both treatment arms considered above (13, 14).

Over the last few decades, an awareness of the above variety of factors and patient demographics have resulted in recent multiple studies trying to elucidate the effect of the two treatment arms discussed with regard to sub populations of adults and also timing of intervention (15, 16, 17).

In designing questions related to patient outcomes, particularly in symptom and function dependent conditions such as lumbar stenosis, specific questions, pertaining to specific subgroup of patients beyond age (e.g. adult versus pediatric), gender, and diagnosis type (e.g. congenital versus degenerative) need to be clarified. It is impossible for current static low back pain classification systems geared toward short term outcomes accurately determine dynamic long term benefits (18, 19, 20).

With regard to guidelines and policies that are government-sponsored, patient-centered outcome studies and recommendations, there is heterogeneity of both medical specialty society recommendations and also that of the medical payer policies due to variations in the literature and also transparency in the development of the policies (21).

In formulating questions on patient-centered outcomes related to function, quality of life, pain or adverse events, due to the complexity of the subject, variation of beneficiaries and lack of effective long term data, it is important to have clearly identified subgroups and also quality studies across specialty/ society groups identifying specific outcomes to avoid erroneous generalizations.

3. For adults with low back pain attributed to degenerative spondylolisthesis of the lumbar spine, does spinal fusion differ from nonoperative treatment in the ability to improve:
   a. Patient-centered outcomes such as function, quality of life, or pain?
   b. Adverse events?

Several studies have compared fusion surgery to non-operative treatment for the indication of degenerative spondylolisthesis. These studies have shown that for patients who suffer from low back pain due to degenerative spondylolisthesis, surgical intervention in the form of fusion surgery is more effective than non-operative treatment. Weinstein et al showed in the SPORT trial that surgical intervention for the treatment of degenerative spondylolisthesis showed significant improvement in SF-36 for bodily pain and physical function, as well as statistically significant improvement in the Oswestry Disability Index (29). These improvements were maintained for a follow-up of four years.

With regards to surgical complication rate, Sansur et al reviewed over 10,000 patients with degenerative and isthmic spondylolisthesis for complication incidence and factors associated with adverse events (28). The total rate of complications was 9.2 percent, and included dural tears, wound infections, hardware and implant complications, and neurological complications. Factors that correlated with a higher complication rate included higher grade spondylolisthesis, and age > 65 years old. Degenerative spondylolisthesis had a higher complication rate than isthmic spondylolisthesis (8.5 percent vs. 6.6 percent, p=0.002). These complication rates do not differ significantly from those in other series published in the literature (40, 41, 42, 43). The complication rate for patients undergoing surgical intervention for degenerative spondylolisthesis, while obviously higher than the complication rate of non-surgical treatment, are consistent with complication rates for spine surgery in general, and should not be a deterrent to pursuing surgical intervention, which provides longer term and more definitive treatment of back pain for degenerative spondylolisthesis.

Lumbar fusion has been shown in multiple studies in the literature to be a more effective treatment for degenerative spondylolisthesis, and provides improvement in pain and disability that is superior to conservative therapy.

4. For adults with low back pain attributed to degenerative disc disease of the lumbar spine, does spinal fusion differ from other spinal procedures (e.g., total disc replacement, disc decompression) in the ability to improve:
   a. Perioperative outcomes such as surgery time, blood loss, or length of hospital stay?
   b. Patient-centered outcomes such as function, quality of life, or pain?
   c. Adverse events?

It is unclear from well executed randomized prospective trials that there is any difference between lumbar arthroplasty and lumbar fusion in operative treatment of patients with lumbar degenerative disc disease (DDD). Approval of lumbar arthroplasty by the U.S. Food and Drug Administration was predicated upon establishing parity in clinical outcomes with the standard of care, lumbar fusion. The FDA used the criterion of non-inferiority as the foundation for approving lumbar arthroplasty devices for widespread use (25).

A prospective randomized comparative trial of lumbar arthroplasty versus lumbar fusion assigned 72 adult DDD patients to posterolateral fusion (PLF) or posterior lumbar interbody fusion (PLIF) at 1-2 levels. Back pain and ODI scores decreased significantly at 2-years. At 2-years, 76 percent of fusion patients were back to work part or full time and 67 percent were satisfied with their surgery (26). A meta-analysis performed by Bono and Lee reviewed all publications on non-revision fusion for lumbar DDD from during a 20 year period, encompassing over 2000 patients. They report good or excellent clinical outcomes were achieved in over 70 percent of those treated (27).

Disc decompression, dynamic stabilization, facet replacement and many other evolving technologies do not have substantial literature support to allow comment on the relative efficacy of these procedures compared to lumbar fusion.

There are significant complications which may occur in patients undergoing lumbar spine fusions. Previous reports have not found a significant difference between arthroplasty and arthrodesis study cohorts. Disc degeneration may occur in segments adjacent to fusions in the lumbar and cervical spine. It is unclear whether or not these areas of “juxtafusional” disease are caused by the neighboring fusion or if they represent the natural progression of the lumbar and cervical degenerative processes.

These well designed and well executed studies have not demonstrated any differences in patient outcomes. It seems unlikely that further investigations will be superior to these efforts. Observational patient registries may be one means to answer these questions.

5. For adults with low back pain attributed to degenerative stenosis of the lumbar spine, does spinal fusion differ from other spinal procedures (e.g., decompressive laminectomy and minimally invasive procedures, including those using devices) in the ability to improve:
   a. Perioperative outcomes such as surgery time, blood loss, or length of hospital stay?
   b. Patient-centered outcomes such as function, quality of life, or pain?
   c. Adverse events?

Degenerative stenosis has diverse etiologies, and for Key Question #5 we must assume that the question is restricted to patients without an underlying need for spinal fusion such as in patients with spinal deformity or spondylolisthesis. Low back pain associated with degenerative stenosis without spinal instability or expected iatrogenic instability, such as in patients with spinal deformity or spondylolisthesis, does not alter the recommendations of decompressive laminectomy alone with targeted use of medial facetectomies and foraminotomies, with or without discectomy. Decompressive laminectomy has been supported for superiority over non-operative therapy in degenerative stenosis by

studies such as the SPORT trial. This randomized, prospective trial indicated substantially greater improvement in pain and function through 4 years after decompressive surgery (44).

The 2005 AANS/CNS guidelines on this topic noted that spinal fusion procedures are associated with improved outcomes in patients with pre-operative evidence of spinal instability (45). Hopp and Tsou first introduced the impact of iatrogenic instability occurring during surgery due to extensive facetectomy necessary to achieve decompression in 1988 (46). Subsequent reports have supported the concept (47, 48). Fox et al reported extensive decompression at more than one level without concomitant arthrodesis was associated with worse outcomes following decompressive laminectomy for lumbar degenerative spinal stenosis (48). The AANS/CNS Guidelines for Lumbar Fusion formally endorsed spinal fusion in addition to decompressive laminectomy under those circumstances of iatrogenic instability (45).

Minimally invasive options for the treatment of lumbar degenerative stenosis have gained widespread use but its rapid evolution has made its evaluation a moving target. There is extensive literature on the clinically utility of minimally invasive surgery as a safe and effective for the treatment of degenerative lumbar stenosis. Studies have indicated that minimally invasive spine surgery and traditional open lumbar surgery have similar long-term patient outcomes in terms of pain and quality of life (52, 55, 56). Studies and meta-analyses on peri-operative factors have reported equivalence in complication rates for minimally invasive surgery, with minimally invasive surgery associated with a lower post-operative wound infection, less intra-operative blood loss, longer operative times, with overall no difference in long-term patient outcomes (50, 51, 52). Fourney et al reported a systematic review in 2010 indicating no difference in adverse events (rates of reoperation, dural tear, cerebrospinal fluid leak, nerve injury, and infection) between minimally invasive lumbar decompression and open surgery, with or without fusion (49). Two more recent literature review and cost analysis studies suggested lower infection rates (and lower associated costs) for minimally invasive surgery (53, 54).

Laminectomy and other decompressive procedures are not generally performed for the treatment of axial low back pain. These procedures are performed to treat claudication or radiculopathy, with lumbar fusions indicated if there is pre-operative or expected intra-operative iatrogenic spinal instability.

6. For adults with low back pain attributed to spondylolisthesis of the lumbar spine, does spinal fusion differ from other spinal procedures (e.g., repair, vertebrectomy) in the ability to improve:

a. Perioperative outcomes such as surgery time, blood loss, or length of hospital stay?

b. Patient-centered outcomes such as function, quality of life, or pain?

c. **Adverse events?**

The main treatment options for adult spondylolisthesis are decompression with fusion. Treatment of spondylolisthesis with fusion is the most common approach, and is the most clearly documented surgical option in the literature. The largest series reported is from the Scoliosis Research Society, where they reported the results of 10,242 surgically treated cases of adult spondylolisthesis. Out of 10,242 patients, only 532 were treated without fusion (28). Complications rates in patients undergoing fusion versus those undergoing decompression alone were not significantly different (28). In the SPORT trial, the vast majority of patients in the surgical group (who had superior outcomes when compared to the non-operative group) had fusions (29). The reason why this disease is treated mostly through fusion is due to reported risks of deformity progression and chronic pain in patients treated without fusion. Herkowitz demonstrated a high failure rate after decompression without fusion, and better outcomes with fusion (30). Other studies also support fusion in the treatment of this disease over other surgical options (31, 32).

Direct repair of the fractured pars interarticularis (spondylolysis) without fusing adjacent segments is a potential treatment option, but is limited to very minimal degrees of slip in younger patients who would have a better chance for bone formation along the fractured pars. A few studies report direct repair of the fractured pars, but there are no well recognized studies comparing pars repair to fusion, as the circumstances under which one would actually be able to consider pars repair alone are rare (33, 34). As discussed in the question, vertebrectomy is mentioned as a possible surgical alternative. Vertebrectomy would be reserved for very rare and severe circumstances of spondylolisthesis from trauma or oncologic conditions. Again due to the relative rarity of such situations, it cannot even be considered as a comparable treatment option in the routine patient with back pain and or leg symptoms from spondylolisthesis.

Since fusion remains the dominant treatment of choice in this condition, and as it has repeatedly been shown that fusion has more optimal results than decompression alone, it may not be useful to check for differences in perioperative outcomes such as surgery time, blood loss, or length of hospital stay. More long term outcomes, such as re-operation rates and long term quality of life measures have demonstrated that fusion is the superior treatment. Other options such as direct repair of pars, and vertebrectomy are indicated in rare circumstances and hence are not to be considered as comparable entities.

7. **For adults with low back pain attributed to degenerative disc disease of the lumbar spine, do spinal fusion approaches (e.g., anterior, posterior, combined) and techniques (e.g., instrumentation or graft material) differ in the ability to improve:**
   a. **Perioperative outcomes such as surgery time, blood loss, or length of hospital stay?**
   b. **Patient-centered outcomes such as function, quality of life, or pain?**
   c. **Adverse events?**

Clinicians understand that more involved procedures, such as combined anterior/posterior fusions, generally entail longer surgery, greater blood loss, and longer hospital stays. They are usually employed, however, in selected patients who are thought, prospectively, to be at risk for a suboptimal outcome from an alternative procedure because of individual patient factors or particular aspects of the patient's pathology. Many of these important differences, such as osteoporosis, significant motion on flexion/extension radiographs, or segmental kyphosis, are not routinely identified and studied in directly comparative investigations. On the contrary, most RCTs and other studies strive to achieve or to demonstrate complete balance between treatment cohorts and therefore treat differences between patients as potential sources of bias rather than as possible key indicators of the likely benefit of one technique over another.

For example, in the treatment of spondylolisthesis, there are several fusion techniques commonly employed including non-instrumented fusion, posterior instrumentation with posterolateral fusion (PLF), posterior instrumentation with interbody fusion, or a combined anterior and posterior approach. Each of these approaches has a role in the treatment of a heterogeneous patient population. An elderly patient with a collapsed disc space and a relatively fixed deformity would likely do well with a non-instrumented fusion whereas a younger patient with a more mobile spine would be at high risk for failure of that fusion construct and would be better treated with a more aggressive approach. The influence of spinal alignment, local anatomical features, osteoporosis, and patient demand (i.e. activity level and age) cannot be overstated. Evidence to this point is provided by Soegaard et al who found that circumferential fusion (the most costly and morbid) was associated with significant benefits and cost savings compared to less aggressive techniques in a working population (Soegaard et al: Circumferential fusion is dominant over posterolateral fusion in a long term perspective. Spine 32: 2405-2411, 2007). It is quite possible, indeed likely, that this benefit would not be apparent in an older patient population.

8. For adults with low back pain attributed to degenerative stenosis of the lumbar spine, do spinal fusion approaches (e.g., anterior, posterior, combined) and techniques (e.g., instrumentation or graft material) differ in the ability to improve:
   a. Perioperative outcomes such as surgery time, blood loss, or length of hospital stay?
   b. Patient-centered outcomes such as function, quality of life, or pain?
   c. Adverse events?

The response for Key Question #8 mirrors the discussion of Key Question #2. There are diverse indications for fusion in the setting of stenosis, and the approach varies with the diverse pathology and involved patient population. The use of fusion in the setting of stenosis is typically considered when instability is demonstrated pre-operatively or anticipated based on preoperative/intraoperative factors. In these circumstances, lumbar fusion has been shown to be beneficial, with improved function, quality of life, and pain. For symptomatic spinal stenosis with or without degenerative spondylolisthesis, a recent systematic review by Chou et al. found evidence that decompressive surgery is moderately superior to nonsurgical therapy through 1 to 2 years. Surgery for radiculopathy in the setting of symptomatic spinal stenosis is associated with short-term benefits compared to nonsurgical therapy, though benefits diminish with long-term follow-up in some trials. For nonradicular back pain with common degenerative changes, fusion is no more effective than intensive rehabilitation, but is associated with small to moderate benefits compared to standard nonsurgical therapy (10).

As highlighted in other Key Question responses, spinal fusions of any nature can increase surgery time, blood loss, potential for adverse events, and length of hospital stay, in comparison with simple decompression. It is understood by physicians that combined anterior-posterior fusion surgery will typically result in greater intraoperative time, blood loss, and length of hospital stay, and higher risk for adverse events – and that it is typically reserved for patients felt to be at risk for poor outcomes via a more limited approach (so as to improve functional or quality outcomes than would otherwise be expected). The superiority of a particular approach (anterior, posterior, combined) or technique (instrumentation or graft material) has not been proven, as the factors involved in a surgeon's decision are heterogeneous; options for approach are not always equal/competitive. Surgical techniques and approaches are constantly being refined. A study trying to prove superiority of one approach is doomed to limited relevance and will undoubtedly be an immense undertaking with likely equivocal outcomes.

9. For adults with low back pain attributed to spondylolisthesis of the lumbar spine, do spinal fusion approaches (e.g., anterior, posterior, combined) and techniques (e.g., instrumentation or graft material) differ in the ability to improve:
   a. Perioperative outcomes such as surgery time, blood loss, or length of hospital stay?
   b. Patient-centered outcomes such as function, quality of life, or pain?
   c. Adverse events?

The question put forth by AHRQ regarding the relative efficacy of the various spinal fusion approaches to address low back pain in patients with spondylolisthesis is far too broad a question in the expansive diagnosis of spondylolisthesis to conclusively answer. While examination of the various surgical approaches for a single diagnosis may seem at first glance appear to be a valid question for a homogeneous cohort, in reality spondylolisthesis is far from uniform. This diagnosis has within it various subsets and anatomical considerations that make it a heterogeneous group and therefore difficult to study.

For example, in the treatment of spondylolisthesis, several fusion techniques are commonly employed including non-instrumented fusion, posterior instrumentation with posterolateral fusion (PLF), posterior

instrumentation with interbody fusion, or a combined anterior and posterior approach. Each of these approaches has a role in the treatment of a heterogeneous patient population. An elderly patient with a collapsed disc space and a relatively fixed deformity would likely do well with a non-instrumented fusion whereas a younger patient with a more mobile spine would be at high risk for failure of that fusion construct and would be better treated with a more aggressive approach. The influence of spinal alignment, local anatomical features, osteoporosis, and patient demand (i.e. activity level and age) cannot be overstated. Evidence to this point is provided by Soegaard et al who found that circumferential fusion (the most costly and morbid) was associated with significant benefits and cost savings compared to less aggressive techniques in a working population (Soegaard et al: Circumferential fusion is dominant over posterolateral fusion in a long term perspective. Spine 32: 2405-2411, 2007). It is quite possible, indeed likely, that this benefit would not be apparent in an older patient population.

The largest and most expensive trial to date is the NIH funded Spine Patient Outcomes Research Trial (SPORT). While this trial represents the most comprehensive study to date examining the 3 common fusion methods used in the treatment of degenerative spondylolisthesis, it was not specifically designed to evaluate the three fusion techniques of posterolateral in situ fusion, posterolateral fusion with pedicle screw fixation and 360º fusion (PLIF/TLIF, ALIF augmented with pedicle screw stabilization). Regardless, this trial represents the largest cohort of degenerative spondylolisthesis available for review. The preliminary SPORT data demonstrated that individuals with spinal stenosis and associated degenerative spondylolisthesis treated surgically had substantially greater improvement in pain and function during a period of 4 years than did patients treated nonoperatively (29, 35). A subsequent evaluation of fusion methods within the same study attempted to examine the outcomes of 3 different fusion techniques: PLF, PPS and 360º fusion, but were unable to establish superiority of one approach over another. This is not because the procedures are equivalent, it is because they were each applied in appropriate patient populations and were generally successful.

With regards to the perioperative outcomes of surgery time and blood loss, times ranged from 157 to 274 minutes, with PLF having the shortest operative time and 360º having the longest. Mean blood loss ranged from 499 to 666 ml, again with PLF averaging the lowest and PPS averaging the highest. The most common adverse event was a dural tear, which was highest for PPS (12%) followed by PLF (9%) and lowest in 360º (2%). Incidentally, the rate of an inadvertent durotomy in this report seemed inordinately high. By comparison, Williams and colleagues reported a durotomy rate of 1.9 percent in patients with spondylolisthesis in their review of 108,478 cases (36). The postoperative transfusion rate in the SPORT study followed the same trend, PPS (26%), 360º (17%) and PLF (14%).

With regards to patient centered outcomes, all three groups' demonstrated significant improvement compared to baseline in various validated outcome measures (ODI, SF-36 BP and BF). There was no significant difference between the groups at 4 years (37). It is again important to emphasize that the SPORT study was not specifically designed to evaluate fusion techniques or to validate one form of fusion for the management of degenerative spondylolisthesis. While prospective in design, there was no randomization and therefore the results may have been affected by selection bias. Only a prospective randomized study designed and appropriately powered to evaluate these three fusion techniques in a narrow population with specific anatomical criteria has the capacity to determine which fusion method provides the greatest improvement in outcome measures and is the most cost effective treatment. However, the SPORT data has demonstrated the effectiveness if surgical treatment compared with nonsurgical treatment of degenerative spondylolisthesis.

While there is a constellation of reports in the literature that explore some element of the various subsets of question 9, there is no comprehensive study that unequivocally answers this question and, for the various reasons listed above, we do not foresee such a study ever taking place. What the literature has

unequivocally demonstrated is that surgeons have effectively used all three of these approaches to successfully treat patients with spondylolisthesis.

10. Are there patient characteristics (e.g., pain severity, prior treatment) that are associated with better or worse outcomes after spinal fusion?
   a. Patient-centered outcomes such as function, quality of life, or pain
   b. Adverse events

Some patient characteristics may have an effect on outcomes after spinal arthrodesis for lumbar degenerative disease. However, to date, no study has determined definitive preoperative characteristics which may predict optimal or suboptimal outcomes from lumbar arthrodesis. Several smaller studies and meta-analyses have reported preoperative parameters which may be included in the overall evaluation when considering a patient as a candidate for lumbar arthrodesis.

For example, psychiatric comorbidities have been examined as a potential predictor of outcomes. A recent meta-analysis evaluated outcomes from both nonsurgical and fusion treatments to examine the effect of psychiatric comorbidities on outcomes. While there were few studies specifically addressing this question, those studies suggested that patient whose comorbidities include a personality disorder, depression, or neuroticism should preferentially be treated non-operatively (15). Others have corroborated that the presence of depression may be an independent predictor of success for surgery (20). However, as Daubs et al. report, the strength of their recommendation is weak. While there are no definitive studies that would preclude surgery as an option for patients with psychiatric comorbidities, the studies cited suggest that it should be evaluated during decision making.

Other factors have been looked at as well, including preoperative health status, cardiac comorbidity, and work status among others. Preoperative health status self-assessment appears to be the most robust, yet definitive criteria for predicting outcome have not been established (38). Other factors such as radiographic findings have been explored as well. In general, when findings such as spondylolisthesis are present, these have been reported to portend a better outcome (9).

Overall, current literature does not support criteria or strong recommendations for excluding spinal arthrodesis due to specific preoperative patient characteristics (39).

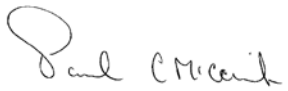
Conclusion

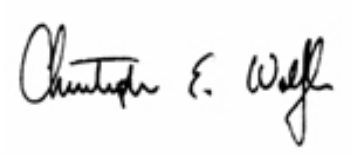
We appreciate the opportunity to comment on the Key Question formulation regarding the AHRQ proposed research on the topic of "***Spinal Fusion for Painful Lumbar Degenerative Disc or Joint Disease***". The AANS and CNS developed clinical guidelines on this topic in 2005, and we are currently undergoing the process of updating these guidelines. Based on our experience, we do not believe that another systematic review of these questions will yield useful information as there is a paucity of sufficient data and the quality of the studies is limited. **After reviewing the current literature in conjunction with the clinical expertise of our Neurosurgeon members, the AANS and CNS do not believe that this diminishes the benefit of this surgical treatment to our patients.** While we understand that these AHRQ research summaries are not clinical recommendations or guidelines, we remained concerned that this research proposal will involve a large effort with minimal and limited clinical relevance.

Again, thank you for this opportunity to comment and we look forward to seeing your final position pertaining to this proposed research. If you have any questions, please feel free to contact Joseph

Cheng, MD (joseph.cheng@vanderbilt.edu), AANS/CNS Committee for Payor and Policy Responses, or Koryn Rubin, the AANS/CNS Senior Manager for Quality Improvement.

Sincerely,





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WellPoint, Inc.
Medical Policy Questionnaire

January 17, 2012

Policy Number: SURG.00130
Policy Title: Annulus Closure After Discectomy

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical on the topic of **Annulus Closure After Discectomy**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We are seeking input addressing (1) the need for annular closure after discectomy and (2) the clinical impact for the use of devices designed for annular closure.

We have designed our process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. At the same time, your feedback and the feedback we receive from others on this topic may be shared with non-WellPoint entities, including a national association ("Association") and its constituents. This will allow your input to be considered as WellPoint, Inc. formulates its medical policy positions, which affect the more than 33 million members enrolled in our plans, by an even broader audience on behalf of the Association and the many millions of Americans whose health care benefits are provided by its member plans.

Attached is the ***draft version*** of the medical policy.

We will carefully review your responses to the questions below and we welcome additional insights you provide on this topic. Please be sure to:

- **Answer all questions**
- **Complete the conflict of interest**
- **Complete the demographic information and release statement on the following page**
- **Provide peer-reviewed literature citations when changes to a policy position are suggested**

Thank you for supporting our process to maintain medical necessity determinations consistent with the principles of evidence-based medicine by providing your expertise, guidance and input.

Please complete the information on the following page.

Please return your comments to: Barbara Brown at technology.compendium@wellpoint.com on or before February 14, 2012.

The following information is needed for this review.

Reviewer Name: *(Note: Include credentials)*	Joseph S. Cheng, MD, MS
Board Certification in: *(Note: BC is required)*	Neurological Surgery
Academic/Hospital Affiliation(s):	Vanderbilt University
Address:	T-4224 Medical Center North, Nashville, TN 37232
State(s) of Medical Licensure:	Tennessee, Wisconsin
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Date:	February 6, 2012

Conflict of Interest	**Yes**	**No**	**Comments**
Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with devices for annular repair? If so, please disclose that relationship.		X	

Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if WellPoint, Inc. may release the following points of information to the committee(s) and non-WellPoint entities, including a national Association.

	Yes	**No**	**Comments**
Name of your Academic/Hospital Affiliation(s)	X		
Your Name	X		

AANS

Policy Number: SURG.00130 Policy Title: Annulus Closure After Discectomy Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
General questions:			
Is the **DESCRIPTION** clear and accurate? If no, please comment.	X		
Is the **POLICY POSITION** clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment		X	Repair of the annulus after microdisctectomy is not a procedure that is separately reportable per CPT, and considered an inherent component of the surgical procedure. This is an intraoperative tool based on surgeon preference, such as using staples instead of sutures for the dura or placing fibrin sealant over the dura to prevent scarring. As annular repair by any means is not a separately reportable procedure, there is a lack of data on its efficacy as it would be difficult to analyze.
Is the **RATIONALE** clear and does it accurately reflect the currently available medical evidence? If no, please comment.		x	Comments as noted above related to the policy position.
Specific questions regarding the Policy determination:			
Therapeutic Interventions: • The policy indicates that *annulus closure devices are* considered **investigational and not medically necessary** *for annulus repair after discectomy.* - Do you agree?		X	Repair of the annulus after microdiscectomy has been performed by surgeons in a variety of methods. These include healing by secondary intention, which is the typical method, placement of fat in the opening, placement of gelatin foam or sponge in the opening, opening of the annulus in a rectangular fashion to create a flap, placement of a barrier device such as Adcon-L or a spinal membrane, etc.
• Do you consider devices for annulus repair after discectomy **medically necessary**? - If yes, please comment on specific criteria (or conditions) which would be useful in selecting appropriate patient populations and cite literature to support.	X		As noted above, closure of any wound by primary or secondary intention has been a surgical decision based on the expected needs of the patient.
• If you answered the two questions preceding this one to indicate "Yes" that annulus closure using devices after discectomy is both **investigational and medically necessary**, please explain. If you did not answer in that manner, response is not required.			
• Are there any specific clinical or patient characteristics for when the use of devices for annulus repair after discectomy is not appropriate? - If yes, please comment and cite literature to support.		X	
• Is there evidence to support one technique/device for annulus closure over another? - If yes, please comment and cite literature to support.		X	
Improved Patient Outcomes: • Is there adequate evidence to demonstrate that the use of devices for annulus closure after discectomy provides significant improvement in	X		Asymptomatic same-site recurrent disc herniation after lumbar discectomy: results of a prospective longitudinal study with 2-year serial imaging. Lebow RL, Adogwa O, Parker SL, Sharma A,

Policy Number: SURG.00130 Policy Title: Annulus Closure After Discectomy			
Definitions of Medically Necessary and Investigational included in Exhibit I			
	Yes	**No**	**Comments**
clinical outcomes compared to the available alternatives?			Cheng J, McGirt MJ. Spine (Phila Pa 1976). 2011 Dec 1;36(25):2147-51. A prospective cohort study of close interval computed tomography and magnetic resonance imaging after primary lumbar discectomy: factors associated with recurrent disc herniation and disc height loss. McGirt MJ, Eustacchio S, Varga P, Vilendecic M, Trummer M, Gorensek M, Ledic D, Carragee EJ. Spine (Phila Pa 1976). 2009 Sep 1;34(19):2044-51. Recurrent lumbar disc herniation after single-level lumbar discectomy: incidence and health care cost analysis. Ambrossi GL, McGirt MJ, Sciubba DM, Witham TF, Wolinsky JP, Gokaslan ZL, Long DM. Neurosurgery. 2009 Sep;65(3):574-8; discussion 578. Recurrent disc herniation and long-term back pain after primary lumbar discectomy: review of outcomes reported for limited versus aggressive disc removal. McGirt MJ, Ambrossi GL, Datoo G, Sciubba DM, Witham TF, Wolinsky JP, Gokaslan ZL, Bydon A. Neurosurgery. 2009 Feb;64(2):338-44; discussion 344-5. Review. An evidence-based review of the literature on the consequences of conservative versus aggressive discectomy for the treatment of primary disc herniation with radiculopathy. Watters WC 3rd, McGirt MJ. Spine J. 2009 Mar;9(3):240-57. Epub 2008 Sep 21. Review.
• Is there additional *peer-reviewed literature,* other than that cited in the policy, to demonstrate improved patient outcomes due to the use of devices for annulus closure after discectomy? - If yes, please comment and cite literature to support.		X	
Is there *other information* you feel is relevant regarding the *medical necessity* of this technology?		X	

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" services are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a covered individual for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the covered individual's illness, injury or disease; and
- not primarily for the convenience of the covered individual, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that covered individual's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

"Investigational" means that the procedure, treatment, supply, device, equipment, facility or drug (all services) does not meet the WellPoint Technology Evaluation Criteria because it does not meet **one or more** of the following criteria:

- have final approval from the appropriate government regulatory body; or
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- be proven materially to improve the net health outcome; or
- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.

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January 30, 2012

Washington State Health Care Authority
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Subject: Draft Health Technology Assessment: BMP for Spinal Fusion

To Whom it May Concern:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we would like to thank the Washington State Health Care Authority for the opportunity to comment on the draft Health Technology Assessment (HTA) regarding the use of recombinant human Bone Morphogenetic Protein (rhBMP2 and rhBMP7). We appreciate the efforts of your team in developing a very thorough review of the published literature reporting on the use of BMP as an adjunct to spinal fusion.

We believe rhBMPs are a comparably safe and effective bone graft alternative appropriate in patients with medical indications as determined by their treating surgeon. FDA approval of the on-label indications of rhBMP noted equivalent or superior fusion rates, shorter operative times, and decreased bone graft donor site complications. Our assessment of the literature would indicate that rhBMPs are appropriate bone graft options for single level anterior (ALIF) and posterior (PLIF) lumbar interbody fusion, and can also be considered an appropriate bone graft substitute in single-level posterolateral lumbar fusion.

The HTA approaches assessment of BMPs through addressing 5 “Key Questions.” For clarity, our comments will parallel the approach of the HTA authors.

Key Question 1: Expected Treatment Outcomes and Validated Instruments

The Washington HTA identified three outcomes measures most commonly used in the literature: Short Form 36 (SF-36), Oswestry Disability Index (ODI) and Visual Analogue Pain Scale (VAS). Of these, only the SF-36 has been evaluated for validity in spinal fusion patients. There is a paucity of validated outcome measures of minimal clinically important difference for spinal fusion patients to compare rhBMP to autograft and allograft.

The metrics used in the assessment of patients undergoing lumbar fusions have been used for decades and are well accepted. In development of the National Neurosurgery Quality and Outcomes Database (N2QOD) by the AANS, outcome measures were chosen to develop a collaborative reporting mechanism to assess the extent lumbar spinal surgery improves pain, disability, and quality of life, while adjusting for bias and influential confounders, including variances in co-morbidity, surgical approach, cultural factors, region, structure and process of health services. Furthermore, risk-adjusted benchmarks of surgical

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morbidity and effectiveness, which define spine surgical quality, are being developed as well. In the N2QOD model, VAS, ODI, Euro-Qol 5D (EQ-5D), and the NASS Patient Satisfaction Index (PSI) were considered to provide an optimal foundation for future study design.

Key Question 2: Evidence of Efficacy and Effectiveness of BMP

The HTA reviews the level of evidence in the available literature concerning the efficacy and effectiveness of rhBMP-2 and rhBMP-7 for on-label and off-label uses in the lumbar and cervical spine. The authors conclude that no evidence was found to support the use of rhBMP-7 for posterolateral lumbar spine fusion or cervical fusion given the absence of literature on those topics. They have identified varying levels of evidence to support both the efficacy and effectiveness for the use of on-label and off-label rhBMP-2 in the lumbar and cervical spine as well as off-label use of rhBMP-7 in the lumbar spine.

As noted in the report, there are large systemic reviews assessing the use of rhBMP in lumbar fusions. These reports echo the conclusions of our societies, finding that rhBMP is an effective tool to facilitate lumbar fusion in single level procedures and may be considered an effective substitute to autograft or allograft. It should also be taken into consideration that many of the initial BMP studies were powered to demonstrate non-inferiority. Through this early experience, spine surgeons have gained greater proficiency in use of rhBMPs and have begun to modify their clinical use. It is our expectation that the level of evidence supporting use of biologics in spinal fusion will continue to rise as our experience using these agents matures.

Key Question 3: Safety of On- or Off-Label Use of rhBMP

We agree with the Washington HTA's review that reported adverse events related to BMP use are either low or very low in incidence. The largest reported series of BMP use comes from the Scoliosis Research Society Database analyzing complications in over 55,000 patients undergoing fusion surgery. Out of this patient population, over 11,900 patients received BMP. With the exception of anterior cervical surgery, overall complication rates were not significantly different between patients receiving BMP and those not receiving BMP (8.4% vs. 8.5%; $P = 0.5$). A concern is also with heterotopic bone formation, such as with off-labeled use in posterior lumbar interbody fusions. The study by Haid et al did identify an increased heterotopic bone graft formation (71% versus 12%), but did not find this clinically relevant in their patients (a).

However, in anterior cervical fusions where BMP was used, overall complications were more common (5.8% vs. 2.4%; $P < 0.001$). Multivariate analysis for anterior cervical spinal fusion also verified the increased complication rate, even after adjusting for the effects of patient age and revision surgery status. In regards to a reported increase in death rates in anterior cervical surgery with use of rhBMP, this was not identified to be statistically significant. However, since the reporting of such severe adverse events, rhBMP has been used in conjunction with steroids in this context to reduce excess inflammation during the peri-operative period (b).

Any potential adverse effect of BMP use should be weighed against those of autograft and allograft. Iliac crest bone grafting and harvest has a well -known morbidity with patient complaints of pain related to the harvesting of iliac crest bone, which may be permanent. With the exception of anterior cervical spine fusion, the present literature does not support that complication rates in patients undergoing spine fusion with BMP (on label or off label) are significantly higher than those patients undergoing autograft harvest. Beyond random anecdotal case reports and editorial opinions, there is no clear literature that provides a causal relationship between BMP use and increased risk of complications, except in the aforementioned cervical cases.

Key Question 4: Evidence of Differential Efficacy or Safety for Spinal Fusion

The Washington HTA reports that there is "no strong evidence of the differential effectiveness of spinal fusion using rhBMP-2 or rhBMP-7 versus ICBG or alternative bone graft substitutes in any subpopulation". Specific subpopulations included in this Key Question had been in the exclusion criteria of many studies, as characteristics such as tobacco use and multi-level or complex spinal fusions are known potential risk factors for failure of fusion. Recombinant human BMP-2 and rhBMP-7 clinical efficacy studies have generally excluded subjects with these characteristics.

However, as noted in Glassman et al, smokers undergoing posterolateral lumbar fusion had a 95.2% fusion rate in the rhBMP group compared to only a 76.2% fusion rate with autogenous bone (c). Additional studies of lesser quality such as by Slosar have denoted the potential of rhBMP-2 as a graft extender in higher risk patients, such as smokers, with rhBMP-2 having a 0% nonunion rate per level compared to a 22.2% nonunion rate per level for smokers who did not receive rhBMP-2 (d).

The benefit of enhancing fusion for patients with complex underlying conditions extends to those undergoing multilevel revision and spinal deformity surgery. Obtaining autogenous iliac crest bone graft may be limited in patients requiring multilevel revision or deformity surgery secondary to either previously harvested ilium or the need to secure iliac fixation. The lack of Level I evidence to support the use of BMP for specific subpopulations does not discount its potential benefit.

Key Question 5: Cost Implications and Cost-Effectiveness of On- or Off-Label Use

Acknowledging the associated costs of BMP as a product (including merchandise, processing and handling of implant) are greater than that of autograft, there have been a number of variables cited for the cost effective use of rhBMP such as shorter operating room time, shorter hospital stay, fewer revision surgery needs, more rapid mobilization of postoperatively, and, at least anecdotally, faster return to work.

Glassman et al. published two studies in 2008 documenting the cost-effectiveness of BMP in spinal surgery in comparison to iliac crest bone autograft). In patients over 60 years of age, there were more complications and additional treatments in the autograft group compared to those who received BMP. Overall costs of admission (first and second admissions, both and individually) were nearly the same between autograft and BMP. In a second study, the authors concluded that the hospital carries the cost burden for using BMP in lumbar fusions, but cost savings include decreased payment for in-patient rehabilitation and improved hospital reimbursement by decreasing the length of stay, physician costs, and outpatient services in the first three months following surgery (the standard global period). The cost for the first admission was greater for BMP versus autograft ICBG, but all other costs were greater for the autograft ICBG group versus the BMP group: physician costs, postoperative inpatient rehabilitation, and total combined costs (e).

In a cost analysis of lumbar fusion in Germany, France and England, overall cost-savings offset the upfront price for BMP. Savings were mainly achieved by reduced productivity-loss due to faster return-to-work time for patients treated with BMP in anterior lumbar fusion. Improved patient clinical outcomes combined with better health economic outcomes for the society support BMP as a valuable alternative compared to autograft (f).

Further study is appropriate to assess the effectiveness, both in clinical and cost parameters, of BMP in other spinal disorders, including long segment fusions, subtypes of fusions, and specific subpopulations of patients with poor bone quality and/or advanced age. As the candidacy for surgical intervention widens, peri-operative factors available to optimize and to improve healing will doubtlessly be valued.

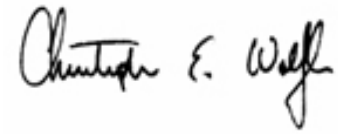
Conclusion

We appreciate the opportunity to review the draft Washington HTA. Thank you for considering our comments. We recognize that rhBMP is a costly technology and is not appropriate for the majority of spinal fusion procedures.

After review of the current literature, the AANS and CNS believe rhBMP remains a viable alternative to autograft and allograft for clinically appropriate cases, as chosen by treating surgeons. The full potential of rhBMP as an adjunct to spinal fusion cannot be determined by the current literature. It is almost certain that there are a number of patients for whom rhBMP will maximize the potential for a successful clinical outcome and restoration of an acceptable quality of life.

Again, thank you for this opportunity to comment and we look forward to seeing your final position pertaining to the use of recombinant human Bone Morphogenetic Protein (rhBMP2 and rhBMP7). If you have any questions, please feel free to contact John Ratliff (John.Ratliff@jefferson.edu) or Joseph Cheng, MD (joseph.cheng@vanderbilt.edu), Committee for Payor and Policy Responses, or Cathy Hill, Senior Manager, Regulatory Affair AANS/CNS (chill@neurosurgery.org).

Sincerely,



Paul C. McCormick, MD, MPH, President
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Christopher E. Wolfla, MD, President
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The goal of the NeuroPoint Alliance (NPA) is to coordinate a variety of projects related to the collection, analysis and reporting of clinical data relevant to neurosurgical practice. Such activities include, but are not limited to, data collection for the following purposes: American Board of Neurological Surgery (ABNS) Maintenance of Certification (MOC) practice data requirements; Medicare Physician Quality Reporting System (PQRS) reporting requirements; industry-sponsored registry reporting; specific clinical outcome research projects; and other quality improvement initiatives led by private payers and national quality consortia.

As a first step, we are in the process of recruiting an initial group of practice sites to participate in a pilot that will serve as a foundation for a broader National Neurosurgery Quality and Outcomes Database (N^2QOD). The primary aim of this pilot is to demonstrate the feasibility of nationwide aggregate data collection with a high degree of validity and quality control. The pilot will initially focus on degenerative lumbar spine disease, but our goal is to expand the number and type of neurosurgical procedures/diagnoses over time. Under the guidance of an ad hoc Spine Subcommittee, the N2QOD's Scientific Advisory Committee (**roster attached**) recently reached consensus on an initial set of data variables (**also attached**) that will be used under the pilot. We are working with a highly respected health informatics company, Outcomes, Inc., to provide an online data-entry system, as well as the Vanderbilt Institute for Medicine and Public Health (VIMPH) to perform back-end statistical analyses of the data and provide individualized feedback reports to practices. We hope to launch the pilot by the end of the second quarter of 2011.

To date, 25 sites have expressed interest in participating in the pilot, including UCSF, Hopkins, and Columbia (but not Brigham/Harvard). While this core group represents practices committed to carrying this project forward, no legal contracts have been signed yet. We hope to formalize contracts between the NPA and participating centers over the next month or so. The annual cost is expected to be in the range of $10,000 per center, but the final cost will depend on how many sites join the pilot. We expect the initial centers contributing to the pilot to remain major stakeholders in the registry's further development and for their annual costs to be discounted in future years as the registry opens for nationwide involvement.

Interested pilot sites were recently asked to identify clinical, business, and data manager representatives whom the NPA leadership could communicate with regarding updates and next steps. Your practices have identified the following representatives:

Practice Site	Clinical Representative	Business Representative	Data Manager
Columbia	Peter Angevine, MD	Evan Johnson	
Johns Hopkins	Ali Bydon, MD Ziya Gokaslan	Barbara Levit Ziya Gokaslan	Barbara Levit Ziya Gokaslan, MD
UCSF	Praveen Mummaneni, MD Phil Weinstein, MD	Bob Gruner Mayra Sustaita	Erika Caccia

We also recently distributed templates for each site to submit for IRB review, which I can send you if interested. We anticipate that most IRBs will declare the N2QOD as a non-research quality improvement program and therefore, IRB-exempt.

Finally, as Matt mentioned, we are holding a series of planning meetings during the April AANS annual meeting in Denver. We'd greatly appreciate if you could join us for our Scientific Committee meeting. Details follow:

N^2QOD Scientific Committee
Sunday, April 10, 2011
2:30pm-3:30 pm
Hyatt Regency, Denver, Centennial Ballroom A

Please let me know at your earliest convenience if you are able to attend this meeting.

If you have any additional questions about this effort, please feel free to contact me, Tony Asher, Vice President of the NPA and Director of the N^2QOD, at asher@cnsa.com or Matthew McGirt, Vice Director of the N^2QOD, at matt.mcgirt@vanderbilt.edu.

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Executive Committee

Officers and Committee Chairs

JOINT SECTION ON DISORDERS OF THE SPINE & PERIPHERAL NERVES

September 2011-12

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Chair Elect	Joseph.cheng@vanderbilt.edu	J. Cheng
Immediate Past Chair	Zgokasl1@jhmi.edu	Z. Gokaslan
Secretary	vmum@aol.com	P. Mummaneni
Treasurer	jhurlber@ucalgary.ca	J. Hurlburt
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Annual Meeting Chair	Daryl.fourney@saskatoonhealthregion.ca	D Fourney
Scientific Program Chair/cmte	mwang@mcw.edu	Marj Wang
Exhibit Chair/Cmte	Mwang2@med.miami.edu Dsciubb1e@jhmi.edu Dj_hoh@yahoo.com khamilton@smail.umaryland.edu cis8z@virginia.edu rhaid@atlantabrainandspine.com	Mike Wang D Sciubba D Ho K Hamilton C Shaffrey R Haid
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Membership Committee	Pda9@columbia.edu	P. Angevine
Outcomes Committee Chair	Zoher.ghogawala@yale.edu	Z. Ghogawala

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Past Chair's Cmte Liason	Jtalexan59@yahoo.com	J. Alexander

Minutes for Spine Section Executive Committee Meeting
October 3, 2011
Washington, DC
Members Present:
Guests:
The meeting was called to order by Dr.Cheng at 1145 am and Dr. Wolfla concurred at 1150 am.

1. Secretary's report P. Mummaneni
a. Review and approval of minutes
b. Informational items
- Survey -- "Defining Complications" J. Ratliff - John wants to table his survey for now.

- Survey -- "Spinal Deformity" C. Ames – A 10-20 question survey to quantitate the neurosurgical knowledge gap in spinal deformity. Assess the knowledge gaps to plan for educational activities. Funding for the survey may be $2000-$3000, and could come through either AANS or Spine Section. Survey monkey is another option and costs $1000. A third option is to have AANS do a survey during the AANS annual meeting spine section session. Dr. McCormick said the AANS would be happy to cover the cost. Dr. Heary motioned to have AANS conduct this survey during the annual meeting. Dr. Mummaneni seconded. The EC approved.
(C. Shaffrey recommends only 1 survey qo/month)

- Reappointment of Eric Woodard as Section representative to NPA Board of Directors

- Continue $100,000 contribution to NREF for Young Spine Clinician Investigator award for 5 years - Spine Section funded an award for NREF for $400,000 for an endowment. The interest from this endowment is approximately $20,000. This is being used to fund a $40,000 award for spine related issues – half of this amount comes from the interest from the endowment and the other half would need to come from Spine Section.

Dr. Wolfla motions that the spine section give $40,000 to NREF to support the Young Spine Clinician Investigator Award. The NREF will be asked to increase the award to $50,000 as of fiscal year 2012. Seconded by Dr. Mummaneni. EC approved.

- Noridian VP/KP response (**attached) L. Tumialan – Dr. Cheng discussed their coverage of kyphoplasty and vertebroplasty including use for malignancy related pathological fractures. Noridian is considering the appeal from the rapid reaction taskforce.

Action Item: Dr. Cheng will coordinate future position statements with the Rapid Response Group and the Guidelines group.

- ONE Spine endorsement P. Mummaneni – Dr. Mummaneni suggested that ONE Spine faculty be involved in the Spine Section. An update will come to the next EC cmte meeting by Dr. Mummaneni.
- Updated Cervical Spine and SCI Guidelines M. Hadley – A draft copy was given by Dr. Hadley to Dr. Wolfla.

2. Treasurer's Report J. Hurlburt
**Report attached

Year end is June 30, 2011. As of June 30, 2011, the section assets grew from $2.7 million to $3.1 million. Net revenue for 2011 was $400,000 which exceeded the budgeted revenue of $300,000.

3. New business

N2QOD and NPA update was provided by Eric Woodard. N2QOD is up and running now with the work of Zo Ghogawala and Tony Asher.
Eric Woodard's term is finished, but the EC agreed to have him continue on for another year as the Spine Section's representative.

4. Old business
5. Committee Reports
a. Annual Meeting D. Fournay/ M Wang –

Evaluations of the last meeting were excellent. There was very little perception of bias.

The meritorious award winner is Dr. Maiman. The guest country is Brazil. There are two debate sessions, Cahill 1 and Cahill 2 sessions.

Abstracts are now being graded. 279 abstracts were sent in this year compared with 290 last year. There are limited rooms at Swan, so courses have been consolidated. Exhibit hall is going to close Friday evening. Opening reception is to be in exhibit hall. Plan on finalizing abstracts by Oct 8.

b. CPT J. Knightly -
Percutaneous discectomy was being billed in the 63030 code. So the wording for the code was changed.

The ASA asked for support to differentiate a physician versus a health care provider to offer certain CPT services. The CPT cmte has remained neutral on this for now.

There have been issues with billing of one versus multiple paddle electrodes for a single operation. The wording was now changed to a “paddle array”.

The MILD procedure was excluded from the formal CPT laminar decompression code.

Issues related to vertebroplasty and kyphoplasty coding were reviewed by the CPT cmte.

The CPT cmte is looking into interspinous process plating and how to code it.

Xstop will be requested to remain as a Category 3 code.

The Rapid Response Team is working to continue to provide care to patients being denied certain procedures through insurance policies. Joe Cheng is the director and Charlie Sansur will be depuy director. Quadrants will be overseen by Ratliff, Tumialan, Angevine. The members of the Rapid Response Team will also join the CPT cmte. Joe is setting up a formal liason with Blue Cross of Tenn. to provide input into their policies. Blue Cross unilaterally froze their fee schedule in certain areas and also there is now an automatic manual review of spine procedures by some insurance carriers.

Work comp carriers are not following Medicare fee schedule increases for practice expenses in some areas. Joe is working with the task force to evaluate and modify this issue.

Dr. Wolfla proposes an action item to amend the rules and regulations to formalize the Rapid Response team to be a standing cmte in the Spine Section.

c. Exhibits M. Wang - Exhibits hall will close Friday evening instead of Saturday. And the lunch will be in the Exhibit hall on Friday. This is based on the recommendation from the vendor meeting with the Exhibits Cmte.

Opening reception will likely be in the exhibit hall. Dr. Wang will communicate with the CNS meeting folks.

The exhibit hall is larger this year than last year, 1000 added square feet is available and we do not have as many vendors as last year to this point.

There are 7 major educational grant supporters. The “what’s new” session is sold already. Dr. Wang suggested having the Brazilian instrumentation companies also to exhibit. Dr. Justin Smith suggested adding a What’s New session just before the Opening Reception. Dr. Mike Wang will look into this issue.

Styker, Nuvasive, and K2M have not yet paid their support amounts this year.

d. Future sites I. Kalfas/E. Woodard
**Letter attached (re: March 2015 site, AAOS pending)

We may need to alter the 2015 date due to the AAOS having a meeting at a similar time.

Action Item: Dr. Resnick asked

e. Research and Awards A. Kanter
New Fellowship/award guidelines (e.g., Globus)
Globus is willing to fund a research award for Spinal Deformity for $40,000 per year, and the EC wishes Dr. Kanter to pursue this. The naming of the award will be coordinated with Globus.

f. Education F. Lamarca – AANS will have a session on Spine devoted to biologics including controversies related to BMP.
Dr. Jeff Wang from UCLA may be invited to give a talk on basic science of bone issues.

g. Guidelines M. Kaiser – lumbar guidelines drafts are in to Dr. Kaiser.
An update on the tumor mets and lumbar guidelines and the trauma guidelines is pending.

h. Outcomes Z. Ghogawala – Neuropoint SD has completed enrollment (204 patients were enrolled). 94% follow up was achieved. ODI and SF36 showed significant improvements for single level fusions and single level discectomies.

The Clinical Trials awards – the 2008,2009,2010 award winners will present at the Spine Section Annual Meeting to receive the remainder of their funding grants.

i. Peripheral nerve TF A. Bellzberg
Allan Belzberg assumes Chair of PN division

A peripheral nerve cadaver course will be added to the spine deformity resident's course.

j. Publications L. Holly/ J. Dhall
Spine section abstracts report

The JNS: Spine and Neurosurgery both are interested in the Spine Section's platform abstracts.

Dr. Holly asked if we can have a reconsideration of the current plan to go to JNS: Spine.

Dr. Wolfla asked for the JNS Spine and Neurosurgery to submit proposals regarding how they would handle abstracts, platform papers, and guidelines publications. Would they charge the Spine Section for these publications?

Action Item: Dr. Mummaneni, Holly, and Wolfla will draft a letter to the journals.

k. Public Relations M. Steinmetz
l. Membership P. Angevine
m. Washington Committee R. Heary/ K Orrico

Katie discussed the SGR cut of 30% by January 1, 2012 if congress does not act. The super-cmte is considering proposals to achieve $1.5 trillion in deficit savings. To remove the SGR will cost $300 billion. Katie also is working to repeal the IPAB. Washington office has six budgeted staff.

Bob Heary updated the EC regarding a $75K to $100K contribution from the Spine Section to the Washington Cmte. The Washington Cmte has budgeted for $75K from the Spine Section and presumed this money would come through automatically. This budgeted amount from the Spine Section should have been 0 for this year, as it is optional for the Spine Section to contribute. In spite of this one time accounting issue, Dr. Heary proposed to give the Washington Cmte $100K in spite of the Washington Cmte conducting their accounting not in line with the Spine Section's requests.

Dr. Wolfla proposed to give $75K to the Washington Cmte and also provide an extra $25K for a Separate Spine Related Special Projects Account for this fiscal year. Joe Cheng seconded this motion and the EC approved it for one year.

**Report attached (Orrico and Alex Valadka were present)

n. Fellowships M. Wang/ L. Holly

CAST may be reworked. The match is difficult to coordinate and did not go forward this year.

o. Web Site E. Potts – The videos are disappearing from the website. Dr. Potts is coordinating to a new server.

p. CME C. Sansur – Prior Webinars may be made accessible for CME credit in the future. Prior selected lectures may be downloaded for CNS CME credit.

q. Nominating Committee Z Gokaslan – will be reported next time.

r. Rules and Regs J. Smith
SPC & EC member disclosures policy update

- Justin updated regarding the AANS and the CNS current disclosure policies. Justin has discussed these issues with Jamie Ulman and Chris Wolfla by teleconference. The question is what is needed for categorizing dollar amounts. Dr. McCormick and Dr. Wolfla will try to coordinate the AANS and the CNS disclosure efforts.

The Rapid Response Team will be considered to become a standard standing cmte for the Spine Section. This issue will be formalized in the future.

s. Newsletter K. Eichholz – 3 or 4 per year will be done. Just ahead of the major meetings.

t. ASTIM J. Coumans – Nov. 15 is the meeting to develop standards and Dr. Coumans will attend.

u. NREF Gokoslan/ Woodard – nominated John Hurlbert, Bob Heary, and Bob Spinner were nominated by the Spine Section for the NREF executive council.

Last year's NREF spine award winner had to return the funds due to the inability to meet the requirements of the grant.

Dr. Mummaneni and Dr. Wolfla suggest a committee to encourage NREF submissions.
The will be discussed in Orlando – Dr. Resnick and Dr. Mummaneni will brainstorm.

v. AANS PDP K. Foley/ P. Johnson
w. Young Neurosurgeons comm. D. Sciubba/J. Bellotte
x. FDA drugs and devices J. Alexander
y. AMA Impairment G. Trost
z. Inter-Society Liaison M. Rosner – ***Action Item: Rosner and Mummaneni will discuss faculty cooperation with Dr. Lenke for SRS and then report back to the Spine Section EC.***

There being no further business the meeting was adjourned at 2:15 pm.
Respectfully submitted, Praveen Mummaneni, Secretary.