

# CONTINUING EVOLUTION OF CIAS

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## PHARMACEUTICAL MANUFACTURER SETTLEMENTS

©2010 Riordan Consulting LLC	COMPANY	Year	\$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Medicaid Drug Rebate
	TAP	2001	875	X	X	X		
	Bayer I	2001	14		X			X
	Pfizer I	2002	49					X
	AstraZeneca I	2003	600	X		X		
	Bayer II	2003	257					X
	Glaxo	2003	87.6					X
	Pfizer II	2004	430		X		X	
	Schering I	2004	345					X
	Serono	2005	704	X			X	
	King	2005	124					X
	Lilly I	2005	36				X	
	Schering II	2006	435	X	X		X	X
	Intermune	2006	36				X	
	Pfizer III	2007	34.7	X			X	
	Cell Therapeutics	2007	10.5	X	X		X	
	Purdue	2007	635				X	
	Medicis	2007	9.8			X	X	
	Jazz	2007	20			X	X	

**PHARMACEUTICAL MANUFACTURER SETTLEMENTS 2**

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COMPANY	Year	\$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Medicaid Drug Rebate	Unapproved/ Ineffective
Sanofi-Aventis	2007	190	X	X				
BMS	2007	515	X	X		X	X	
Merck	2008	650	X	X			X	
Otsuka	2008	4		X		X		
Biovail	2008	22	X					
Cephalon	2008	425		X		X		
Eli Lilly II	2009	1400		X		X		
Pfizer IV	2009	2300	X	X		X		
Eon (Novartis)	2010	3.5		X				X
Schwarz	2010	22		X				X
AstraZeneca II	2010	520	X	X		X		
Johnson & Johnson	2010	81		X		X		
Novartis Vaccines	2010	72		X		X		
Allergan	2010	600		X		X		
Forest	2010	313	X	X		X		X
Novartis	2010	420	X	X		X		

## MEDICAL DEVICE MANUFACTURER SETTLEMENTS

	COMPANY	Year	\$M	Kickbacks	False Claims	Off-Label Promotion	Adverse Events	Other
©2010 Riordan Consulting LLC	Guidant	2003	94				X	
	Orthofix	2003	1.6		X	X		
	Medtronic	2006	40	X				
	Adv Neuromodulation Sysys	2007	3					
	Zimmer Inc.	2007	169.5	X				
	Depuy Orthopaedics	2007	84.7	X				
	Smith & Nephew Inc.	2007	28.9	X				
	Biomet Orthopedics	2007	26.9	X				
	Stryker Orthopedics	2007	0	X				
	AbTox (went to trial)	2008	17			X	X	
	Medtronic Spine	2008	75		X			
	RJL Sciences	2008	.005		X	X		
	Bayer	2008	97.5	X				
	Neurometrix	2009	3.7	X	X			
	Endoscopic	2009	1	X	X	X		
	Spectranetics	2009	5.0		X	X		X
	Boston Scientific	2009	296		X	X		
	St. Jude	2010	3.9	X	X			
	Cochlear Americas	2010	.880	X	X			
	AtriCure	2010	3.8	X	X	X		
Synthes	2010	23.2			X	X	X	

# INDIVIDUAL LIABILITY

- ❑ **TAP:** 11 individuals (employees and physicians) indicted (dismissed and acquitted)
- ❑ **Serono:** Med. Dir. pled guilty (1 year probation; fined \$150,000); VP Sales, VP Marketing, 2 RDs acquitted
- ❑ **Purdue:** President & COO (\$19M), EVP & General Counsel (\$8M), and Exec. VP of Worldwide R&D (\$7.5M) (pled guilty; 15 year exclusions; sentences pending)
- ❑ **Jazz:** Physician Speaker (arrested, pled guilty to misdemeanor); Rep (convicted of misdemeanor), Rep (pled guilty to felony)
- ❑ **RJL:** President (3 years' probation, \$10,000 fine)
- ❑ **Abtox:** CEO and VP & Chief Compliance Officer (sentenced 10 and 6 years, respectively; plus \$17M in restitution to customers)
- ❑ **Pfizer:** Sales Mgr (sentenced 6 months' home confinement and electronic monitoring, 3 years' probation); Regional Mgr (\$75,000 fine and 24 months' probation)
- ❑ **Stryker:** President charged; 4 Reps pled guilty; 3 others charged
- ❑ **InterMune:** CEO convicted
- ❑ **Synthes:** President of Synthes North America, President of Synthes Spine, Vice President of Operations, Director of Regulatory and Clinical Affairs (pled guilty)

# EVOLUTION OF CIA PROVISIONS

*In the beginning . . .*

- CCO/Compliance Committee
- Written Standards
- Training
- Arrangements Database
- IRO
- Disclosure program (including hotline)
- Screening
- Notifications

# CIA PROVISIONS <sup>2</sup>

*Then Came . . .*

- ❑ Independence of CCO
- ❑ Needs Assessment: consulting services
- ❑ Board Oversight
- ❑ Senior Manager Certification
- ❑ Notification to HCPs
- ❑ Website Postings: payments to HCPs
- ❑ Website Postings: Research/Clinical Studies
- ❑ Inquiries Database
- ❑ Monitoring-Promo
- ❑ Monitoring—Non-Promo
- ❑ Post-marketing Commitments
- ❑ Consultant Monitoring

# CIA PROVISIONS <sup>3</sup>

*And then . . .*

- Needs Assessments: Research
- Needs Assessment: Publications
- Publications Monitoring
- Grants Monitoring
- Compliance Expert
- Website Posting: Med Ed Grants
- Compliance with ICMJE Standards
- Disclosures for Formulary Comm Members

# CONTACT US

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