

Equities

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Global Pharmaceuticals

Who are the Key Players Affected by the \$5.6B U.S. Lipitor LOE?

- **Conclusion:** We assume 3 companies divide branded US Lipitor sales during the 180-day exclusivity period starting Nov 30th, incl. PFE, WPI's authorized generic (AG) & Ranbaxy. We assume PFE retains 40%-50% of branded Lipitor share (\$5.6B last 12 months) by continuing to pass along 40%+ discounts/rebates to mail order/PBM segment, with WPI & Ranbaxy dividing the remaining share at a 50-60% discount. At the end of the 180-day exclusivity period, we assume MYL/TEVA launch along with Dr. Reddy's, Aurobindo, & others, lowering pricing for generic Lipitor to pennies/day. Distributors are expected to benefit from the generic Lipitor mix shift contributing ~\$0.03 in EPS for both ABC & CAH in C2011, & adding ~\$0.06 to MCK. We expect full generic penetration following the exclusivity period, similar to the Zocor LOE (loss of exclusivity) in 2006. Our US cholesterol U.S. market model assumes ~80% of ~350M TRx's are generic by 2012E, making it challenging for remaining branded marketers (AZN's Crestor & MRK's Vytorin franchise) to raise price & gain share (**see Figure 1**).
- **What is the Impact on PFE & WPI Results?** We maintain our PFE 4Q11E/'12E Lipitor sales/EPs contribution at \$930M/\$640M & \$0.07-\$0.09 (14%-18% of 4Q EPS)/ ~\$0.05 (2% of '12 EPS). We estimate that every month delay to Ranbaxy's launch could add <\$0.01 to PFE's '12E EPS (**see Figure 2**). We estimate WPI contribution to sales/EPs at ~\$300M-\$400M/~\$0.48-\$0.53 during the 180 days; if Ranbaxy is delayed by 1-2 months, the EPS benefit could double (**see Figure 3**). Each \$100M in additional generic Lipitor sales (~25-35% GM) adds ~\$0.13-\$0.17 to WPI's EPS (**see Figure 4**).
- **What is the Benefit to Ranbaxy if It Launches on Nov. 30?** Our analyst in India expects generic Lipitor to add cRs30/share to the company's earnings during the 180-day period. This assumes c60% price erosion (higher than what we expected earlier) & 30% share. Post the exclusivity period, we expect higher price erosion (c95%) and lower market share (c20%), translating to full year recurring EPS upside of cRs2/share.
- **What is the Opportunity for Daiichi Sankyo (DS)?** Ranbaxy's issues with FDA/DOJ had been regarded as a major negative factor in the DS's stock price. Our Japanese analyst expects resolutions with several hundred million dollars in fines. Once resolved, investors will take a look at DS's fundamentals rather than simply avoiding the company due to its uncertainty. Generic Lipitor upside is no longer recognized as a huge earnings opportunity given low contribution to Eisai in the generic Aricept case.
- **What is the Benefit to Drug Wholesalers?** We expect the introduction of generic Lipitor to be an incremental positive for the drug wholesalers, with the mix shift contributing ~\$0.03 in EPS for both ABC and CAH in C2011, and adding \$0.06 to MCK. Generic Lipitor should then add \$0.13, \$0.08 and \$0.17 in C2012 for ABC, CAH and MCK respectively, as the wholesalers generate larger profits during the exclusivity period. This will create tougher Lipitor EPS comparisons in C2013, where we estimate generic Lipitor will contribute \$0.05 to ABC, \$0.03 to CAH, and \$0.07 to MCK. [See our teams note on the impact of generic expiries on wholesalers by clicking here.](#)

See Appendix A-1 for Analyst Certification, Important Disclosures and non-US research analyst disclosures.

■ Industry Overview

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- **Generic Wave Should Benefit Drug Retailers in 2H12** — As more generics are introduced, we expect Rx same store sales (SSS) to be pressured, as the average generic drug price is approx. \$35/Rx, versus the average brand name prescription drug price of approx. \$140/Rx. However, we expect the drug retailers to make up some of the loss in average prescription price through increased prescription volume, as more patients are able to afford the Rx. In addition, we believe that the drugstores will be able to generate stronger gross profit dollars as the average gross margin for generic drugs is generally 50 to 60%, while the average gross margin for branded drugs is approx. 20%. As generic exclusivity periods end in 2H12 on some large blockbusters, we expect the drugstores to experience the greatest benefit as their profitability is the highest when three or more generic versions of a drug are in the marketplace.
- **Modest Benefit to Other Generic Companies** — Following the 180-day exclusivity period (assumed to end on May 30th), we assume MYL/TEVA launch along with one other entrant followed by multiple entrants (Dr. Reddy's, Aurobindo, others) over time, compressing pricing for generic Lipitor to pennies per day. We expect full generic penetration following the exclusivity period, similar to the Zocor loss of exclusivity (LOE) in 2006. We assume that the revenue (<\$100M) / EPS contribution for MYL & TEVA are minimal.
- **MRK's Vytorin/Zetia Franchise & AZN's Crestor Franchise Expected to be Under Pressure.** Although the generic statin market will account for a substantial portion of TRx's (~78% by the end of 21012E) following generic Lipitor's launch, we expect AZN to be able to realize increases in net price from 2012 onwards through the clawback of rebates as it looks to capitalize on the installed base of patients that is likely to be sticky. However, the SATURN trial could make it difficult to differentiate high-dose Crestor from high-dose Lipitor in reducing disease progression so new patient growth is likely to slow for Crestor. We anticipate volume pressure for Crestor from 2H12 as plans may keep Crestor's current formulary positioning unchanged in January. For MRK, we see downward pressure to our U.S. Vytorin/Zetia franchise sales. This increases the need for MRK to generate positive results from its IMPROVE-IT trial in mid-2013 (interim look in 1Q12). A favorable result could modestly lessen the impact of managed care plan designs that already strongly encourage the use of generics by either differentiating co-pays or step-therapy requirements for newly diagnosed patients. We model US Vytorin + Zetia sales of \$2.0B (-3% YOY) in 2012E, with each \$200M contributing ~\$0.03 to MRK's earnings.

Figure 1. US Cholesterol Market Model 2006-2015E

Cholesterol Total Prescription Market Model													
Marketer	Launch Date	LOE Date	2006	2007	2008	2009	2010	2011E	2012E	2013E	2014E	2015E	CAGR '10-'15E
Total Cholesterol Market - TRx (000)			265,222	289,244	294,947	311,758	325,103	336,482	348,259	360,448	371,261	382,399	3.3%
% Growth			12.1%	9.1%	2.0%	5.7%	4.3%	3.5%	3.5%	3.5%	3.0%	3.0%	
Total Cholesterol Market - \$ (millions)			\$18,890	\$16,613	\$15,607	\$14,640	\$14,492	\$14,240	\$10,351	\$8,721	\$7,807	\$7,404	-12.6%
% Growth			6%	-12%	-6%	-6%	-1%	-2%	-27%	-16%	-10%	-5%	
Total Generics - TRx (000)			39,089	87,435	113,832	140,954	164,536	198,319	271,111	293,798	309,239	323,371	14.5%
% Share			14.7%	30.2%	38.6%	45.2%	50.6%	58.9%	77.8%	81.5%	83.3%	84.6%	
Total Generics - \$ (millions)			\$1,708	\$1,020	\$1,458	\$1,024	\$895	\$1,245	\$2,429	\$1,745	\$1,202	\$974	1.7%
% Share			9.0%	6.1%	9.3%	7.0%	6.2%	8.7%	23.5%	20.0%	15.4%	13.2%	
Lipitor													
PFE	Jan-97	Nov-11E	94,824	83,814	76,640	68,963	61,797	49,157	2,681	488	399	326	-65.0%
Share of Cholesterol Market			36%	29%	26%	22%	19%	15%	1%	0%	0%	0%	
Implied Price per Rx (\$)			\$83	\$86	\$83	\$82	\$86	\$95	\$104	\$115	\$126	\$139	
US revenue (\$M) (reported/CIR est.)			\$7,849	\$7,195	\$6,332	\$5,667	\$5,329	\$4,663	\$280	\$56	\$50	\$45	-61.5%
% Growth			6%	-8%	-12%	-11%	-6%	-13%	-94%	-80%	-10%	-10%	
Crestor													
AZN	Aug-03	Jul-16E	16,295	19,887	22,087	27,753	31,885	33,993	35,293	30,545	26,432	22,872	-6.4%
Share of Cholesterol Market			6%	7%	7%	9%	10%	10%	10%	8%	7%	6%	
Implied Price per Rx (\$)			\$70	\$72	\$76	\$76	\$83	\$91	\$95	\$99	\$102	\$107	
US revenue (\$M) (reported/CIR est.)			\$1,148	\$1,424	\$1,678	\$2,100	\$2,640	\$3,096	\$3,343	\$3,009	\$2,708	\$2,437	-1.6%
% Growth			57%	24%	18%	25%	26%	17%	8%	-10%	-10%	-10%	
Livalo													
LLY	Jan-92	Jan-16E					83	693	1,613	2,160	2,791	3,116	106.6%
Share of Cholesterol Market							0%	0%	0%	1%	1%	1%	
Implied Price per Rx (\$)							\$145	\$91	\$98	\$105	\$113	\$122	
US revenue (\$M) (reported/CIR est.)							\$12	\$63	\$158	\$227	\$316	\$379	99.5%
% Growth								427%	150%	44%	39%	20%	
Zetia													
MRK	Nov-02	Dec-16E	18,829	21,747	16,934	14,221	12,604	11,286	10,158	9,327	8,733	8,177	-8.3%
Share of Cholesterol Market			7%	8%	6%	5%	4%	3%	3%	3%	2%	2%	
Implied Price per Rx (\$)			\$78	\$81	\$84	\$91	\$97	\$107	\$118	\$130	\$143	\$157	
US revenue (\$M) (reported/CIR est.)			\$1,472	\$1,764	\$1,416	\$1,289	\$1,228	\$1,210	\$1,197	\$1,209	\$1,246	\$1,283	0.9%
% Growth			36%	20%	-20%	-9%	-5%	-2%	-1%	1%	3%	3%	
Vytorin													
MRK	Aug-04	Apr-17E	22,874	28,648	21,501	15,123	11,845	9,046	7,236	6,250	5,682	5,165	-15.3%
Share of Cholesterol Market			9%	10%	7%	5%	4%	3%	2%	2%	2%	1%	
Implied Price per Rx (\$)			\$71	\$74	\$71	\$81	\$91	\$100	\$110	\$121	\$133	\$146	
US revenue (\$M) (reported/CIR est.)			\$1,619	\$2,131	\$1,529	\$1,223	\$1,076	\$904	\$796	\$756	\$756	\$756	-6.8%
% Growth			85%	32%	-28%	-20%	-12%	-16%	-12%	-5%	0%	0%	
Zetia/Lipitor Combo													
MRK	2012E	Apr-17E							455	827	1,315	1,594	
Share of Cholesterol Market									0%	0%	0%	0%	
Implied Price per Rx (\$)									\$110	\$121	\$133	\$146	
US revenue (\$M) (reported/CIR est.)									\$50	\$100	\$175	\$233	
% Growth										100%	75%	33%	
Caduet													
PFE	Feb-04	Nov-11E	2,376	4,070	3,857	3,237	2,606	2,041	785	604	406	274	-36.3%
Share of Cholesterol Market			1%	1%	1%	1%	1%	1%	0%	0%	0%	0%	
Implied Price per Rx (\$)			\$147	\$122	\$127	\$132	\$137	\$143	\$149	\$154	\$161	\$167	
US revenue (\$M) (reported/CIR est.)			\$349	\$497	\$469	\$394	\$339	\$292	\$117	\$93	\$65	\$46	-33.0%
% Growth			94%	42%	-6%	-16%	-14%	-14%	-60%	-20%	-30%	-30%	
Niaspan/Advicor													
ABT	Sept-13E		8,329	8,430	8,879	9,291	9,764	9,013	6,555	3,575	1,392	556	-43.6%
Share of Cholesterol Market			3%	3%	3%	3%	3%	3%	2%	1%	0%	0%	
Implied Price per Rx (\$)			\$77	\$96	\$108	\$111	\$113	\$124	\$137	\$150	\$165	\$182	
US revenue (\$M) (reported/CIR est.)			\$644	\$806	\$960	\$1,034	\$1,102	\$1,119	\$895	\$537	\$230	\$101	-38.0%
% Growth			24%	25%	19%	8%	7%	2%	-20%	-40%	-57%	-56%	
Tricor/Trilipix													
ABT	2012		14,378	15,668	16,388	17,922	17,095	16,231	11,043	7,028	5,111	3,717	-26.3%
Share of Cholesterol Market			5%	5%	6%	6%	5%	5%	3%	2%	1%	1%	
Implied Price per Rx (\$)			\$73	\$73	\$74	\$76	\$77	\$85	\$94	\$103	\$113	\$125	
US revenue (\$M) (reported/CIR est.)			\$1,048	\$1,217	\$1,341	\$1,338	\$1,355	\$1,381	\$1,034	\$724	\$579	\$463	-19.3%
% Growth			13%	16%	10%	0%	1%	2%	-25%	-30%	-20%	-20%	
Tredaptive													
MRK	2013 US									500	1,500	2,625	
Share of Cholesterol Market										0%	0%	1%	
Implied Price per Rx (\$)										\$100	\$100	\$100	
US revenue (\$M) (audited)										\$50	\$150	\$263	
% Growth											200%	75%	
Simvastatin													
Various	Jun-06		16,114	57,726	78,922	98,077	112,985	134,593	135,821	140,575	144,792	149,136	5.7%
Share of Cholesterol Market			6%	20%	27%	31%	35%	40%	39%	39%	39%	39%	
Implied Price per Rx (\$)			\$43	\$12	\$15	\$7	\$5	\$5	\$4	\$4	\$3	\$3	
US revenue (\$M) (audited)			\$687	\$687	\$1,184	\$687	\$577	\$618	\$561	\$523	\$485	\$449	-4.9%
% Growth				0%	72%	-42%	-16%	7%	-9%	-7%	-7%	-7%	
Atorvastatin													
	Nov-11E							3,500	62,687	72,090	79,821	87,952	
Share of Cholesterol Market								1%	18%	20%	22%	23%	
Implied Price per Rx (\$)								\$83	\$25	\$8	\$3	\$3	
US revenue (\$M) (reported/CIR est.)								\$292	\$1,567	\$577	\$267	\$265	
% Growth									436%	-63%	-54%	-1%	
All Others													
			48,229	19,545	14,829	14,295	12,888	6,704	1,329	5,347	8,261	10,606	-3.8%
Share of Cholesterol Market			18%	7%	5%	5%	4%	2%	0%	1%	2%	3%	
Implied Price per Rx (\$)			\$63	\$29	\$29	\$40	\$40	\$40	\$40	\$40	\$40	\$40	
US revenue (\$M) (reported/CIR est.)			\$3,053	\$559	\$424	\$572	\$516	\$268	\$53	\$214	\$330	\$424	-3.8%
% Growth			-45%	-82%	-24%	35%	-10%	-48%	-80%	302%	54%	28%	

Source: Citi Investment Research and Analysis; IMS; Company Reports

Figure 2. PFE: Base and Upside Case Scenarios for Lipitor Sales - 4Q11E & 2012E

	4Q11E	2012E		4Q11E	2012E
Base Case Scenario (Ranbaxy Launches with WPI generic on Time)			Upside Scenario (One-Month Ranbaxy Launch Delay)		
Assumed branded equivalent sales - Lipitor (\$ in million)	\$1,400	\$5,600	Assumed branded equivalent sales - Lipitor (\$ in million)	\$1,400	\$5,600
PFE Portion of Lipitor sales (\$ in millions)	\$933	\$653	PFE Portion of Lipitor sales (\$ in millions)	\$1,000	\$735
% of branded market	66.6%	11.7%	% of branded market	71.4%	13.1%
Gross profit (\$ in millions)	\$905	\$621	Gross profit (\$ in millions)	\$970	\$699
Gross margin	97%	95%	Gross margin	97%	95%
SG&A (\$ in millions)	\$75	\$41	SG&A (\$ in millions)	\$80	\$46
SG&A as % of sales	8.0%	6.2%	SG&A as % of sales	8.0%	6.3%
R&D (\$ in millions)	\$9	\$7	R&D (\$ in millions)	\$10	\$7
R&D as % of sales	1.0%	1.0%	R&D as % of sales	1.0%	1.0%
Pre-tax earnings (\$ in millions)	\$820.7	\$573.5	Pre-tax earnings (\$ in millions)	\$880.1	\$645.1
Taxes	\$232	\$166	Taxes	\$249	\$187
Tax rate	28.3%	29.0%	Tax rate	28.3%	29.0%
Net income from Lipitor (\$ in millions)	\$588	\$407	Net income from Lipitor (\$ in millions)	\$631	\$458
Diluted cash EPS contribution (\$)	\$0.08	\$0.05	Diluted cash EPS contribution (\$)	\$0.08	\$0.06
Diluted shares outstanding	7,735	7,696	Diluted shares outstanding	7,735	7,696
Assumed EPS in model	\$0.49	\$2.35	Assumed EPS in model	\$0.49	\$2.35
% contribution to PFE EPS	15.6%	2.3%	% contribution to PFE EPS	16.7%	2.5%

Source: Citi Investment Research and Analysis

Figure 3. WPI: Base and Upside Case Scenarios for Generic Lipitor (atorvastatin) Sales – 4Q11E & 2012E

	4Q11E	2011E	2012E		4Q11E	2011E	2012E
Base Case Scenario (Ranbaxy Launches its Generic at Same Time)				Upside Case Scenario (Ranbaxy Delays Its Launch by One-Two Months)			
Assumed branded equivalent sales - Lipitor (\$ in millions)	\$1,400.0	\$1,400.0	\$5,600.0	Assumed branded equivalent sales - Lipitor (\$ in millions)	\$1,400.0	\$1,400.0	\$5,600.0
Assumed WPI market share	30.0%	30.0%	21.3%	Assumed WPI market share	50.0%	50.0%	30.0%
Adjusted WPI market share (including stocking)	42.7%	42.7%	17.4%	Adjusted WPI market share (including stocking)	71.2%	71.2%	24.2%
Assumed WPI discount	40.0%	40.0%	69.2%	Assumed WPI discount	40.0%	40.0%	69.2%
WPI generic Lipitor sales (\$ in millions)	\$358.6	\$358.6	\$363.1	WPI generic Lipitor sales (\$ in millions)	\$597.7	\$597.7	\$510.8
Assumed total WPI sales in model (\$ in millions)	\$1,481.5	\$4,511.5	\$5,547.9	Assumed total WPI sales in model (\$ in millions)	\$1,481.5	\$4,511.5	\$5,547.9
% contribution to assumed total WPI sales	24.2%	7.9%	6.5%	% contribution to assumed total WPI sales	40.3%	13.2%	9.2%
Assumed WPI COGS + Royalties (\$ in millions)	\$244.2	\$244.2	\$238.4	Assumed WPI COGS + Royalties (\$ in millions)	\$407.0	\$407.0	\$336.3
WPI gross profit (\$ in millions)	\$114.4	\$114.4	\$124.7	WPI gross profit (\$ in millions)	\$190.7	\$190.7	\$174.5
WPI gross margin	31.9%	32%	34%	WPI gross margin	31.9%	32%	34%
SG&A (\$ in millions)	\$14.3	\$14.3	\$12.3	SG&A (\$ in millions)	\$23.9	\$23.9	\$17.4
SG&A as % of sales	4.0%	4.0%	3.4%	SG&A as % of sales	4.0%	6.7%	4.8%
R&D (\$ in millions)	\$0.0	\$0.0	\$0.0	R&D (\$ in millions)	\$0.0	\$0.0	\$0.0
R&D as % of sales	0.0%	0.0%	0.0%	R&D as % of sales	0.0%	0.0%	0.0%
Other expenses/(income) (\$ in millions)	\$0.0	\$0.0	\$0.0	Other expenses/(income) (\$ in millions)	\$0.0	\$0.0	\$0.0
% contribution	0.0%	0.0%	0.0%	% contribution	0.0%	0.0%	0.0%
Pre-tax earnings (\$ in millions)	\$100.1	\$100.1	\$112.4	Pre-tax earnings (\$ in millions)	\$166.8	\$166.8	\$157.0
Taxes	\$35.0	\$35.0	\$39.4	Taxes	\$58.4	\$58.4	\$55.0
Tax rate	35.0%	35.0%	35.0%	Tax rate	35.0%	35.0%	35.0%
Net income from generic Lipitor (\$ in millions)	\$65.0	\$65.0	\$73.1	Net income from generic Lipitor (\$ in millions)	\$108.4	\$108.4	\$102.1
Diluted cash EPS contribution (\$)	\$0.51	\$0.51	\$0.58	Diluted cash EPS contribution (\$)	\$0.85	\$0.85	\$0.81
Diluted shares outstanding	127.1	127.1	126.7	Diluted shares outstanding	127.1	127.1	126.7
Assumed diluted EPS in model (\$ in millions)	\$1.67	\$4.66	\$5.86	Assumed diluted EPS in model (\$ in millions)	\$1.67	\$4.66	\$5.86
% contribution to assumed total WPI EPS	30.7%	11.0%	9.9%	% contribution to assumed total WPI EPS	51.1%	18.3%	13.8%

Assumes that WPI's generic is priced at 40% discount to brand during 180-day period of exclusivity and at 90% discount thereafter. Assumes WPI's generic Lipitor achieves 40% peak market share in Base Case Scenario and 60% peak market share in Upside Case Scenario, respectively.

Note: 4Q11 market share includes contribution from 10 weeks of stocking.

Source: Citi Investment Research and Analysis

Figure 4. WPI 4Q11E EPS Sensitivity (Generic Lipitor market share vs. pricing discount)

		Market Share												
		10.0%	15.0%	20.0%	25.0%	30.0%	35.0%	40.0%	45.0%	50.0%	55.0%	60.0%	65.0%	70.0%
Pricing Discount	15.0%	\$0.24	\$0.37	\$0.49	\$0.61	\$0.73	\$0.86	\$0.98	\$1.10	\$1.22	\$1.34	\$1.47	\$1.59	\$1.71
	20.0%	\$0.23	\$0.34	\$0.46	\$0.57	\$0.69	\$0.80	\$0.92	\$1.03	\$1.15	\$1.26	\$1.38	\$1.49	\$1.61
	25.0%	\$0.21	\$0.32	\$0.43	\$0.54	\$0.64	\$0.75	\$0.86	\$0.97	\$1.07	\$1.18	\$1.29	\$1.40	\$1.50
	30.0%	\$0.20	\$0.30	\$0.40	\$0.50	\$0.60	\$0.70	\$0.80	\$0.90	\$1.00	\$1.10	\$1.20	\$1.30	\$1.40
	35.0%	\$0.19	\$0.28	\$0.37	\$0.46	\$0.56	\$0.65	\$0.74	\$0.83	\$0.93	\$1.02	\$1.11	\$1.20	\$1.30
	40.0%	\$0.17	\$0.26	\$0.34	\$0.43	\$0.51	\$0.60	\$0.68	\$0.77	\$0.85	\$0.94	\$1.02	\$1.11	\$1.19
	45.0%	\$0.16	\$0.23	\$0.31	\$0.39	\$0.47	\$0.55	\$0.62	\$0.70	\$0.78	\$0.86	\$0.93	\$1.01	\$1.09
	50.0%	\$0.14	\$0.21	\$0.28	\$0.35	\$0.42	\$0.49	\$0.56	\$0.63	\$0.71	\$0.78	\$0.85	\$0.92	\$0.99
	55.0%	\$0.13	\$0.19	\$0.25	\$0.32	\$0.38	\$0.44	\$0.50	\$0.57	\$0.63	\$0.69	\$0.76	\$0.82	\$0.88
	60.0%	\$0.11	\$0.17	\$0.22	\$0.28	\$0.33	\$0.39	\$0.45	\$0.50	\$0.56	\$0.61	\$0.67	\$0.72	\$0.78

Note: Market share includes contribution from 10 weeks of stocking.

Source: Citi Investment Research and Analysis

(4568.T; ¥1,373; 2); (ABC.N; US\$36.38; 2); (ARBN.BO; Rs89.55; 1H); (AZN.L; £28.41; 2); (AZN.L; £28.41; Not Rated); (CAH.N; US\$40.90; 1); (MCK.N; US\$78.69; 1); (MRK.N; US\$34.48; 2); (MYL.O; US\$18.49; 1); (PFE.N; US\$19.40; 2); (RANB.BO; Rs452.35; 1H); (REDY.BO; Rs1,590.05; 1); (TEVA.O; US\$38.46; 1); (WPI.N; US\$67.29; 1)

Appendix A-1

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