FDA drug approval and its relation to a pharmaceutical company's stock price

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ABSTRACT

This report identifies the announcement dates of formal approval by the Food and Drug Administration (FDA) for pharmaceutical companies' new drugs. These approvals give the green light for the company to mass-produce and market their new drug. FDA approval announcement dates are reviewed and compared to the underlying companies' stock prices to determine if there is any identifiable and measureable correlation between those approval dates and the stock prices during the month of approval. When the approved drugs present material new benefits over existing available alternatives, FDA approval announcements do have impact on companies' market share price.

Keywords FDA, drug approval, pharmaceutical, stock price

INTRODUCTION

The growth and sustainability of the pharmaceutical industry (Big Pharma) can be attributed to a steady stream of new drugs and therapies. The process of bringing a new drug to market is both costly and time consuming. On average, it takes 10-15 years and can cost well over $1 billion of investment in research and development to bring a new drug to market. Furthermore, the vast majority of drugs fail in the early testing phases and never make it past the preliminary stages and into clinical testing. As a result, significant financial resources must continually be invested into the process of developing new drugs and therapies.

A pharmaceutical company's stock price is, in part, a measure of the drugs it currently markets and sells. Additionally, its value is based on the company's pipeline of potential new drugs winding their way through various stages of internal approval, clinical trials and, ultimately, approval by the Food and Drug Administration (FDA). Patents and other intellectual property rights for drugs currently marketed ensure a steady stream of cash flows for investors. Thus, the basis of the stock price for any individual pharmaceutical company can, in part, be measured on its current product portfolio and the intellectual property rights associated with it, along with its pipeline portfolio of potential new drugs.

On occasion, there may be a headline in the Wall Street Journal or any number of market-watch websites discussing a pharmaceutical company's stock price immediately after the FDA approves a so called "blockbuster" drug, the term for a drug representing significant advancement or breakthrough therapies over those presently available. However, few new drugs are considered blockbusters. Some drugs represent small improvements over those currently available; others are merely an additional entrant with similar characteristics to other drugs already available. This paper examines the effects on pharmaceutical companies' stock price immediately before and after the FDA approves one of its new pipeline drugs. The research will show, over an eleven year study period, the effects of FDA approvals on the stock price of nine of the most prolific new drug marketers within the pharmaceutical industry during that timeframe.

LITERATURE REVIEW

The Value of Diffusing Information

Asaf Manela (2013) discussed how the speed by which information is diffused into the marketplace affects stock price, examining and comparing two drugs; Viagra, which is manufactured and marketed by Pfizer, and Allegra, manufactured and marketed by Sanofi. These two publicly traded companies are two of the larger manufacturers in the pharmaceutical industry. Viagra treats erectile dysfunction while Allegra treats nasal allergies. Despite the fact that each drug will provide similar revenues to its manufacturer, the share price of each will be affected differently immediately after formal approval is announced to the public by the FDA. The difference between the two is because the news about Viagra will diffuse faster; it makes for better conversation. Conversely, the news of Allegra's approval will travel slower. Therefore, the slower traveling news enables more noise which diminishes any measurable effect on stock price caused by the FDA announcement.

Company Stock Prices Before and After Public Announcements for Oncology Drugs

Rothenstein, Tomlinson, Tannock, and Detsky (2011) conducted a trend analysis of stock prices for various pharmaceutical companies during the testing cycle of their experimental oncology drugs, examining the effect on each company's stock price both before and after public announcements. It tracked the effect on the stock price specific to whether each announcement was positive or negative. The research concluded there was a consistent and quantifiable effect based on whether announcements were positive or negative during the complete pre-market testing life cycle of the drug and prior to final FDA approval. This supports the conclusion that a pharmaceutical company's stock price is a combination of both its current product portfolio and the strength and test results of its pipeline portfolio.

Real-Options Valuation for a Biotechnology Company

Kellogg and Charnes (2000) presented a valuation model that could be applied to pharmaceutical companies included in the more broadly-based biotechnology industry. The valuation model used average assumptions based on industry standards when drugs were in early or Phase I testing and little was actually known about the future of the potential drug. However, as a potential drug moved into Phase II and into further clinical trial testing, more definitive assumptions could be made during each ensuing stage. As a drug moved into each subsequent stage, the model could make better assumptions regarding its launch time, market size, and probability of success. Because of this, the model could be used to better determine a pharmaceutical company's valuation during each successive stage of a potential drug's testing cycle.

Market Response to FDA Announcements

Sakar and de Jong (2006) studied the effects of announcements at four distinct points during the FDA's review process for a potential new drug. The research showed that investors adjust expectations throughout the approval process based on FDA announcements. Moreover, the researchers concluded that investors reacted confidently to positive signals during the FDA review process, but that negative signals had impact of a much greater magnitude. This is a logical conclusion and result. Positive news from the FDA indicates the potential drug has a more likely chance of eventually gaining final approval and being brought to market. Conversely, negative news more than likely signals a setback to either the time frame to bring the potential drug to market or, moreover, that the potential drug will never gain final FDA approval.

Wealth Effects of Food and Drug Administration (FDA) Decisions

Bosch and Lee (1994) studied both the positive effects of FDA approvals of new drugs and the negative effects of FDA disciplinary actions on the stock price of a firm, concluding that FDA decisions have a significant effect on a firm's stock price. The study also considered the effects of information leaks from either the FDA or the firm itself, and found that information prior to an official announcement also has an effect on a firm's stock price. This research used an event-study methodology which attempted to isolate the abnormal effect of the event on the stock price exclusive of other market factors taken as a whole.

Do Product Innovation and News about the R&D Process Produce Large Price Changes

and Overreaction? The Case of Pharmaceutical Stock Prices

Perez-Rodriguez and Valcarcel (2012) discussed how innovation during the research and development process impacts the stock price of a pharmaceutical company. The article discussed the relationship between innovation and other news during the research and development process and found that each can have an effect on a pharmaceutical company's stock price. Interestingly, the research article was from the perspective of the global pharmaceutical market and how the American press can affect an international pharmaceutical company's stock price.

DATA AND METHODOLOGY

Detailed drug approval data for the eleven-year period January 1, 2004 through December 31, 2014 was obtained from the FDA's website, and organized by month. Thereafter, the data was aggregated for each pharmaceutical company based on year and month of approval as indicated in Table 1 (Appendix). Subsequently, nine of the top U.S. pharmaceutical companies were chosen for analysis based on revenues. Those nine companies were: Johnson and Johnson, Pfizer, Bristol-Meyers Squibb, Amgen, Biogen, Celgene, Merck, Gilead, and Lilly.

New drug approvals are classified by the FDA into one of three categories. The first, a Priority Review Drug, is denoted by the letter P. This classification indicates a drug that appears to represent an advance over available therapy. The second classification, a Standard Review Drug, is denoted by the letter S. An S classification indicates a drug that appears to have therapeutic qualities similar to those of available existing drugs. If a new drug is not specifically classified as a P or an S, it has no designated classification. Based upon additional research, it was determined this lack of a designated classification code represents a new drug for which there is no current equivalent. These are considered new "blockbuster" drugs. The legend for drug categories used for analysis is demonstrated in Table 2 (Appendix).

Month-end stock prices were obtained for the aforementioned nine companies for the eleven year study period from the Wharton Research Database. Because approval dates can occur at various times during any month, month-end stock prices following approvals were compared to their previous month-end prices to determine price changes during the month of approval. This ensured capture of the effective change in stock price during that month of approval. Thereafter, charts were created for the periods during which any selected company received FDA approval to identify the existence of any correlation between movements in the company's stock price and FDA approval of its new drug (Charts 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, and 1.9 in Appendix). The findings were compiled and presented in tables and charts categorized according to the three FDA classifications described above: no classification (blockbuster), Priority (P), and Standard (S). Results within each FDA classification were then further broken down into relative magnitude of stock price effect associated with the FDA approval date as follows: large decrease (>2% decrease), small decrease (<2% decrease), small increase (<2% increase), and large increase (>2% increase). Based on the analysis of stock price change for the selected nine companies, we found a common minimum 2 percent change in the stock price; thus, a 2 percent change, above or below in the stock price was established as a reasonable measure of significant price change. Any instance in which there were two drug approvals for a particular company in the same month was counted as one data point unless they were in separate FDA classifications.

RESULTS AND DISCUSSION

As indicated in Table 1 and Chart 1 (Appendix), there was a strong correlation between FDA approval and the stock price of a blockbuster drug. There was a total of 13 such drugs for the combined nine companies. The companies' stock price responded with a small or large increase for 10 of these 13 FDA approval announcements (approximately 77%). For the remaining three, two showed a small decrease while the other showed a large decrease. This correlation supports the contention that investors, and the market in general, react positively to FDA approvals of a blockbuster drug.

As indicated in Table 2 and Chart 2 (Appendix), there was also a positive correlation between FDA approval and a Priority Review Drug. There was a combined total of 31 Priority Review Drug approvals for the combined nine pharmaceutical companies during the eleven year study period. Of those, 19 showed a small or large increase in stock price (approximately 61%), 4 showed a small decrease, and the remaining 8 showed a large decrease. This indicates a reasonably strong correlation between FDA approval and a positive effect on the company's market share price, although a somewhat diminished effect compared to the strong positive correlation exhibited by the blockbuster drugs. This was an expected result. Because the Priority Review Drug classification denotes a drug that appears to represent an advance over available therapy but not an entirely new remedy presently unavailable represented by a blockbuster, it makes sense that the Priority Review Drug classification would show a favorable market response, but not as strong as that of a blockbuster.

As indicated in Table 3 and Chart 3 (Appendix), the Standard Review Drug classification consisted of a combined 50 FDA approvals for the nine pharmaceutical companies during the eleven year study period, and yielded results evenly split between stock price increases and decreases (50% increases, 50% decreases), lacking the correlation found for the other two classifications. This was also an expected result, that the Standard Review Drug approvals would have less effect on stock price than either the blockbusters or Priority Drugs, because this classification simply represents a new drug that appears to have therapeutic qualities similar to those of existing drugs. Consequently, such a drug simply represents an additional choice in the marketplace and investors do not respond strongly to such an approval.

CONCLUDING COMMENTS

This research shows a positive correlation between FDA drug approvals and a company's market share price for instances in which the subject drug is either a new remedy or an improvement above existing remedies available in the marketplace. A "blockbuster" classification is viewed by investors as a growth opportunity for the company. As such, the market responds strongly by increasing that company's stock price. There is also a favorable correlation between a Priority Review Drug classification and increases to a company's stock price. However, as expected, a Priority Review Drug approval's impact on stock price is not as strong as that of the blockbuster drug. Lastly, there was no observable correlation between a FDA approval of a Standard Review Drug classification and the companies' stock price. The market exhibited neither a positive or negative stock price reaction to those "lesser drugs". These results support the conclusion that FDA approval does indeed affect a pharmaceutical company's stock price. The differentiating criterion is the classification level of the new drug, and how investors and the market in general perceive the value each respective approval to the recipient company. Drugs representing more significant advancement over existing therapies cause larger

stock price increases than those that do not.

APPENDIX

Table 1

Drug Name and FDA Appl. #	Active Ingredients	NDA Chem. Type *	Review Classification **	Company	Approval Date
Johnson and Johnson					
MEN'S ROGAINE (NDA #021812)	MINOXIDIL	3	S	JOHNSON AND JOHNSON	1/20/2006
WOMEN'S ROGAINE (NDA #021812)	MINOXIDIL	3	S	JOHNSON AND JOHNSON	1/20/2006
Pfizer					
CADUET (NDA #021540)	AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM	4	S	PzFIZER	1/30/2004
CHILDREN'S ADVIL ALLERGY SINUS (NDA #021587)	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	3	S	PFIZER	2/24/2004
CARDURA XL (NDA #021269)	DOXAZOSIN MESYLATE	3	S	PFIZER	2/22/2005
REVATIO (NDA #021845)	SILDENAFIL CITRATE	5	P	PFIZER	6/3/2005
ADVIL PM (NDA #021393)	DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN	4	S	PFIZER	12/21/2005
ADVIL PM (NDA #021394)	DIPHENHYDRAMINE CITRATE; IBUPROFEN	4	S	PFIZER	12/21/2005
EXUBERA (NDA #021868)	INSULIN RECOMBINANT HUMAN	3	S	PFIZER	1/27/2006
ERAXIS (NDA #021948)	ANIDULAFUNGIN	6	P	PFIZER	2/17/2006
GEODON (NDA #021483)	ZIPRASIDONE HYDROCHLORIDE	3	S	PFIZER INC	3/29/2006
CHANTIX (NDA #021928)	VARENICLINE TARTRATE	1	P	PFIZER INC	5/10/2006
TOVIAZ (NDA #022030)	FESOTERODINE FUMARATE	1	S	PFIZER	10/31/2008
REVATIO (NDA #022473)	SILDENAFIL CITRATE	3	S	PFIZER	11/18/2009
ADVIL CONGESTION RELIEF (NDA #022565)	IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	4	S	PFIZER	5/27/2010
HEPARIN SODIUM (NDA #201370)	HEPARIN SODIUM	5	S	PFIZER	7/21/2011
HEPARIN SODIUM PRESERVATIVE FREE (NDA #201370)	HEPARIN SODIUM	5	S	PFIZER	7/21/2011
ADVIL ALLERGY AND CONGESTION RELIEF (NDA #022113)	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	4	S	PFIZER	12/21/2011
INLYTA (NDA #202324)	AXITINIB	1	S	PFIZER	1/27/2012
ELELYSO (NDA #022458)	TALIGLUCERASE ALFA	1	S	PFIZER	5/1/2012
ADVIL (NDA #201803)	IBUPROFEN SODIUM	2	S	PFIZER CONS HLTHCARE	6/12/2012
REVATIO (NDA #203109)	SILDENAFIL CITRATE	3	P	PFIZER	8/30/2012
DOCETAXEL (NDA #202356)	DOCETAXEL	5	S	PFIZER LABS	3/13/2014
Bristol-Myers Squibb					
BARACLUDE (NDA #021797)	ENTECAVIR	1	P	BRISTOL MYERS SQUIBB	3/29/2005
BARACLUDE (NDA #021798)	ENTECAVIR	3	P	BRISTOL MYERS SQUIBB	3/29/2005

Drug Name and FDA Appl. #	Active Ingredients	NDA Chem. Type *	Review Classification **	Company	Approval Date
ORENCIA (BLA #125118)	ABATACEPT			BRISTOL MYERS SQUIBB	12/23/2005
SPRYCEL (NDA #021986)	DASATINIB	1	P	BRISTOL MYERS SQUIBB	6/28/2006
SPRYCEL (NDA #022072)	DASATINIB	6	P	BRISTOL MYERS SQUIBB	6/28/2006
IXEMPRA KIT (NDA #022065)	IXABEPILONE	1	P	BRISTOL MYERS SQUIBB	10/16/2007
YERVOY (BLA #125377)	IPILIMUMAB			BRISTOL MYERS SQUIBB	3/25/2011
NULOJIX (BLA #125288)	BELATACEPT			BRISTOL MYERS SQUIBB	6/15/2011
ELIQUIS (NDA #202155)	APIXABAN	1	P	BRISTOL MYERS SQUIBB	12/28/2012
REYATAZ (NDA #206352)	ATAZANAVIR SULFATE	3	P	BRISTOL MYERS SQUIBB	6/2/2014
OPDIVO (BLA #125554)	NIVOLUMAB			BRISTOL MYERS SQUIBB	12/22/2014
Amgen					
SENSIPAR (NDA #021688)	CINACALCET HYDROCHLORIDE	1	P	AMGEN	3/8/2004
VECTIBIX (BLA #125147)	PANITUMUMAB			AMGEN	9/27/2006
NPLATE (BLA #125268)	ROMIPLOSTIM			AMGEN	8/22/2008
PROLIA (BLA #125320)	DENOSUMAB			AMGEN	6/1/2010
XGEVA (BLA #125320)	DENOSUMAB			AMGEN	6/1/2010
BLINCYTO (BLA #125557)	BLINATUMOMAB			AMGEN	12/3/2014
Biogen					
TYSABRI (BLA #125104)	NATALIZUMAB			BIOGEN IDEC	11/23/2004
TECFIDERA (NDA #204063)	DIMETHYL FUMARATE	1	S	BIOGEN IDEC INC	3/27/2013
PLEGRIDY (BLA #125499)	PEGINTERFERON BETA-1A			BIOGEN IDEC INC	8/15/2014
Celgene					
VIDAZA (NDA #050794)	AZACITIDINE	1	P	CELGENE	5/19/2004
REVLIMID (NDA #021880)	LENALIDOMIDE	1	P	CELGENE	12/27/2005
THALOMID (NDA #021430)	THALIDOMIDE	6	S	CELGENE	5/25/2006
ISTODAX (NDA #022393)	ROMIDEPSIN	1	S	CELGENE	11/5/2009
POMALYST (NDA #204026)	POMALIDOMIDE	1	S	CELGENE	2/8/2013
OTEZLA (NDA #205437)	APREMILAST	1	S	CELGENE CORP	3/21/2014
OTEZLA (NDA #206088)	APREMILAST	1	S	CELGENE CORP	9/23/2014
Merck					
VIOXX (NDA #021647)	ROFECOXIB	6	S	MERCK	3/26/2004

Drug Name and FDA Appl. #	Active Ingredients	NDA Chem. Type *	Review Classification **	Company	Approval Date
CLARINEX (NDA #021300)	DESLORATADINE	3	S	MERCK SHARP DOHME	9/1/2004
CLARINEX D 24 HOUR (NDA #021605)	DESLORATADINE; PSEUDOEPHEDRINE SULFATE	3	S	MERCK SHARP DOHME	3/3/2005
ASMANEX TWISTHALER (NDA #021067)	MOMETASONE FUROATE	3	S	MERCK SHARP DOHME	3/30/2005
FOSAMAX PLUS D (NDA #021762)	ALENDRONATE SODIUM; CHOLECALCIFEROL	4	S	MERCK	4/7/2005
CLARINEX-D 12 HOUR (NDA #021313)	DESLORATADINE; PSEUDOEPHEDRINE SULFATE	5	S	MERCK SHARP DOHME	2/1/2006
ZOLINZA (NDA #021991)	VORINOSTAT	1	P	MERCK	10/6/2006
JANUVIA (NDA #021995)	SITAGLIPTIN PHOSPHATE	1	S	MERCK SHARP DOHME	10/16/2006
CYANOKIT (NDA #022041)	HYDROXOCOBALAMIN	3	P	MERCK SANTE SAS	12/15/2006
JANUMET (NDA #022044)	METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE	4	S	MERCK SHARP DOHME	3/30/2007
ISENTRESS (NDA #022145)	RALTEGRAVIR POTASSIUM	1	P	MERCK SHARP DOHME	10/12/2007
EMEND (NDA #022023)	FOSAPREPITANT DIMEGLUMINE	2	S	MERCK AND CO INC	1/25/2008
TEMODAR (NDA #022277)	TEMOZOLOMIDE	3	S	MERCK SHARP DOHME	2/27/2009
DULERA (NDA #022518)	FORMOTEROL FUMARATE; MOMETASONE FUROATE	4	S	MERCK SHARP DOHME	6/22/2010
VICTRELIS (NDA #202258)	BOCEPREVIR	1	P	MERCK SHARP DOHME	5/13/2011
JUVISYNC (NDA #202343)	SIMVASTATIN; SITAGLIPTIN PHOSPHATE	4	S	MERCK SHARP DOHME	10/7/2011
ISENTRESS (NDA #203045)	RALTEGRAVIR POTASSIUM	3	P	MERCK SHARP DOHME	12/21/2011
JANUMET XR (NDA #202270)	METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE	3	S	MERCK SHARP DOHME	2/2/2012
LIPTRUZET (NDA #200153)	ATORVASTATIN CALCIUM; EZETIMIBE	4	S	MERCK SHARP DOHME	5/3/2013
NOXAFIL (NDA #205053)	POSACONAZOLE	3	S	MERCK SHARP DOHME	11/25/2013
ISENTRESS (NDA #205786)	RALTEGRAVIR POTASSIUM	3	P	MERCK SHARP DOHME	12/20/2013
NOXAFIL (NDA #205596)	POSACONAZOLE	3	P	MERCK SHARP DOHME	3/13/2014
ASMANEX HFA (NDA #205641)	MOMETASONE FUROATE	2	S	MERCK SHARP DOHME	4/25/2014
ZONTIVITY (NDA #204886)	VORAPAXAR SULFATE	1	S	MERCK SHARP DOHME	5/8/2014

Drug Name and FDA Appl. #	Active Ingredients	NDA Chem. Type *	Review Classification **	Company	Approval Date
BELSOMRA (NDA #204569)	SUVOREXANT	1	S	MERCK SHARP DOHME	8/13/2014
KEYTRUDA (BLA #125514)	PEMBROLIZUMAB			MERCK SHARP DOHME	9/4/2014
Gilead					
TRUVADA (NDA #021752)	EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE	4	P	GILEAD	8/2/2004
EMTRIVA (NDA #021896)	EMTRICITABINE	3	P	GILEAD	9/28/2005
RANEXA (NDA #021526)	RANOLAZINE	1	S	GILEAD	1/27/2006
ATRIPLA (NDA #021937)	EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE	4	P	GILEAD	7/12/2006
LETAIRIS (NDA #022081)	AMBRISENTAN	1	P	GILEAD	6/15/2007
CAYSTON (NDA #050814)	AZTREONAM	3	S	GILEAD	2/22/2010
COMPLERA (NDA #202123)	EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR DISOPROXIL FUMARATE	4	P	GILEAD SCIENCES INC	8/10/2011
VIREAD (NDA #022577)	TENOFOVIR DISOPROXIL FUMARATE	3	P	GILEAD SCIENCES INC	1/18/2012
STRIBILD (NDA #203100)	COBICISTAT; ELVITEGRAVIR; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE	1	S	GILEAD SCIENCES INC	8/27/2012
SOVALDI (NDA #204671)	SOFOSBUVIR	1	P	GILEAD SCIENCES INC	12/6/2013
ZYDELIG (NDA #205858)	IDELALISIB	1	S	GILEAD SCIENCES INC	7/23/2014
ZYDELIG (NDA #206545)	IDELALISIB	1	P	GILEAD SCIENCES INC	7/23/2014
VITEKTA (NDA #203093)	ELVITEGRAVIR	5	S	GILEAD SCIENCES INC	9/24/2014
TYBOST (NDA #203094)	COBICISTAT	5	S	GILEAD SCIENCES INC	9/24/2014
HARVONI (NDA #205834)	LEDIPASVIR; SOFOSBUVIR	1	P	GILEAD SCIENCES INC	10/10/2014
Lilly					
ALIMTA (NDA #021462)	PEMETREXED DISODIUM	1	P	LILLY	2/4/2004
ZYPREXA (NDA #021253)	OLANZAPINE	3	S	LILLY	3/29/2004
CYMBALTA (NDA #021427)	DULOXETINE HYDROCHLORIDE	1	S	LILLY	8/3/2004
ALIMTA (NDA #021677)	PEMETREXED	6	S	LILLY	8/19/2004
CYMBALTA (NDA #021733)	DULOXETINE HYDROCHLORIDE	6	P	LILLY	9/3/2004
EVISTA (NDA #022042)	RALOXIFENE HYDROCHLORIDE	6	S	LILLY	9/13/2007
CYMBALTA (NDA #022148)	DULOXETINE HYDROCHLORIDE	6	S	LILLY	6/13/2008
ADCIRCA (NDA #022332)	TADALAFIL	6	S	ELI LILLY CO	5/22/2009
EFFIENT (NDA #022307)	PRASUGREL HYDROCHLORIDE	1	P	ELI LILLY AND CO	7/10/2009
ZYPREXA RELPREVV (NDA #022173)	OLANZAPINE PAMOATE	3	S	ELI LILLY CO	12/11/2009

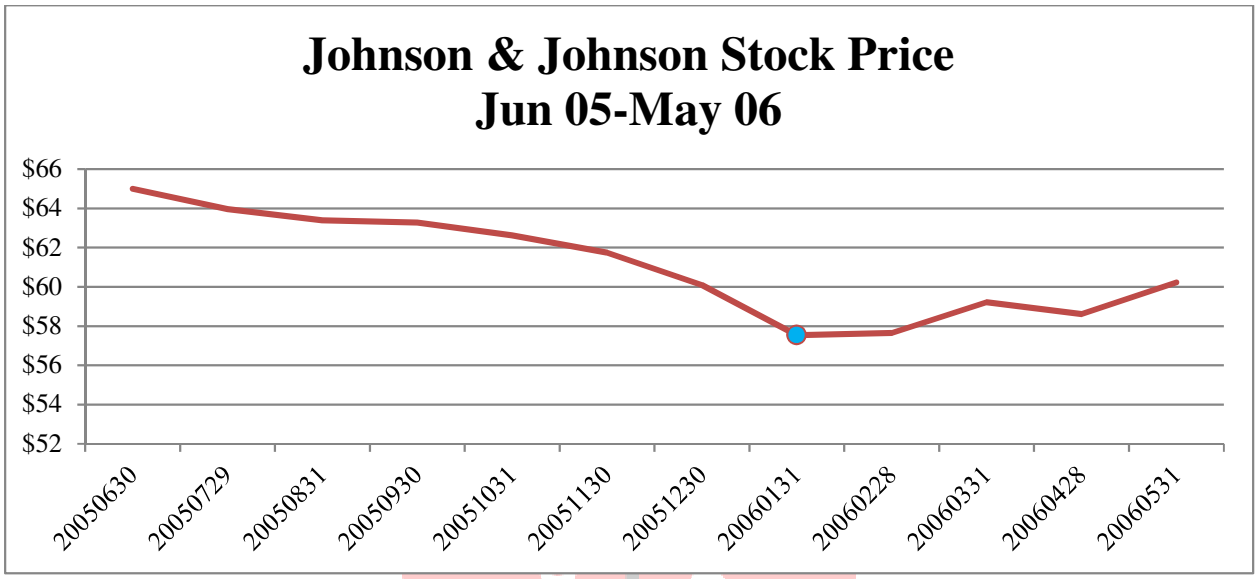
Drug Name and FDA Appl. #	Active Ingredients	NDA Chem. Type *	Review Classification **	Company	Approval Date
CYMBALTA (NDA #022516)	DULOXETINE HYDROCHLORIDE	6	S	LILLY	11/4/2010
AXIRON (NDA #022504)	TESTOSTERONE	3	S	ELI LILLY AND CO	11/23/2010
CYRAMZA (BLA #125477)	RAMUCIRUMAB			ELI LILLY AND CO	4/21/2014
TRULICITY (BLA #125469)	DULAGLUTIDE			ELI LILLY AND CO	9/18/2014

Table 2

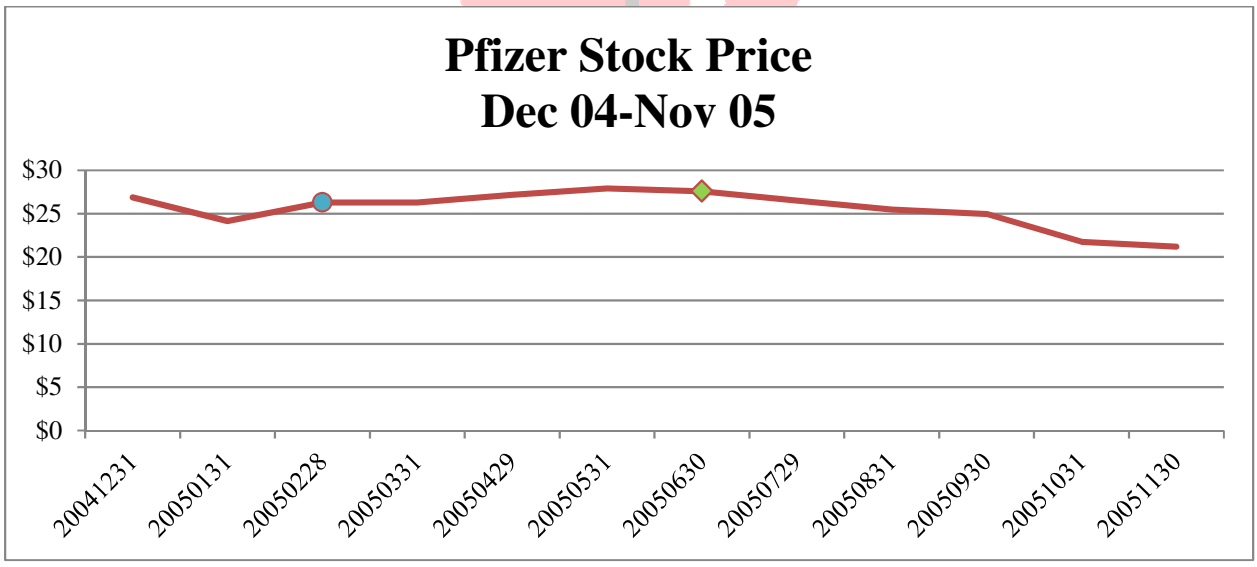
Legend for Graphs		
Symbol	**Codes Represented**	**Description**
		No code was given. Drugs that have no current equivalents(Blockbuster Drugs)
	P	Priority review drugs. Drugs that represent an advance on drugs currently available
	S	Standard review drugs. Drugs that appear similar to currently available drugs.
	P and S	This symbol was used when both a Priority and a Standard drug appeared in the same period.

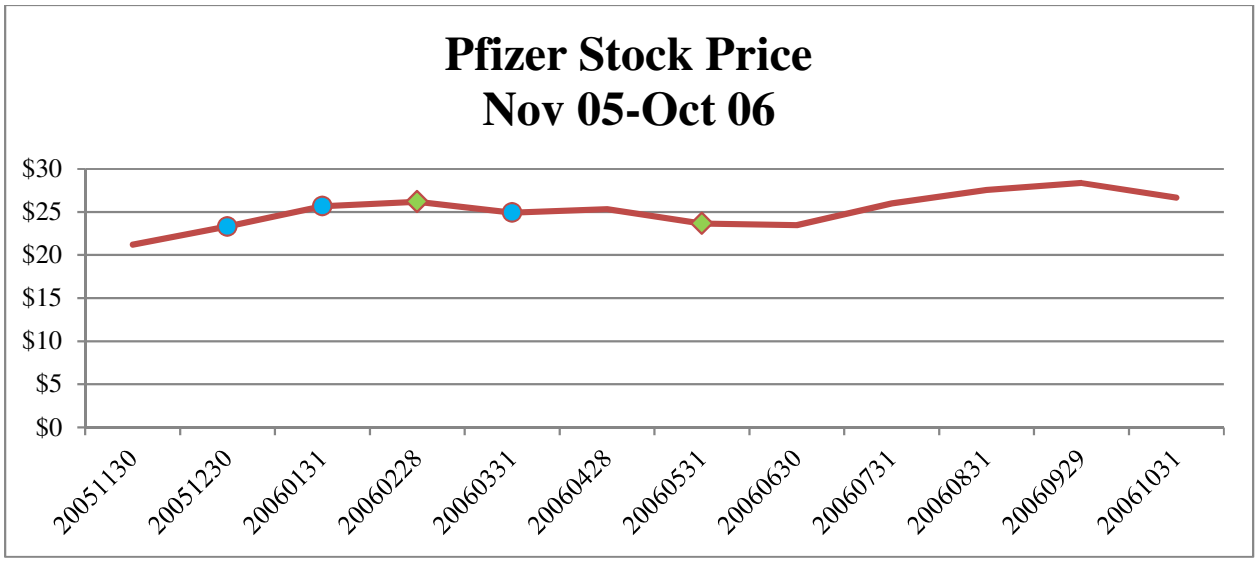
Chart 1 series

1.1 Johnson and Johnson's Stock price change based on the drug approval data from Table 1 above



1.2 Pfizer's Stock price change based on the drug approval data from Table 1 above




Pfizer Stock Price
Nov 05-Oct 06
$30
$25
$20
$15
$10
$5
$0
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20051230
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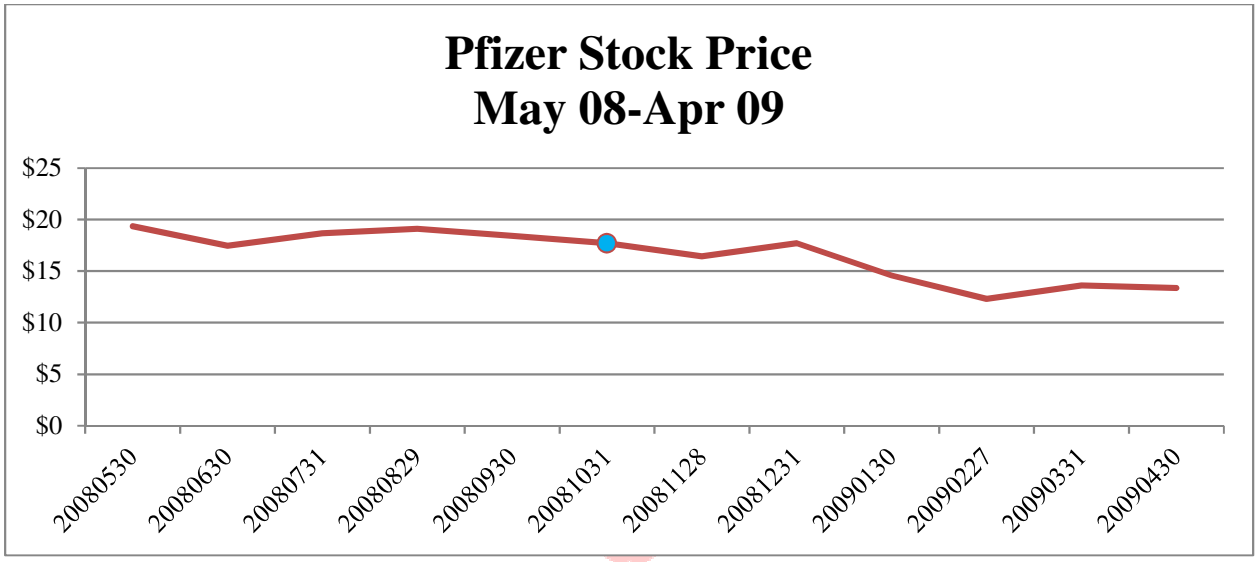
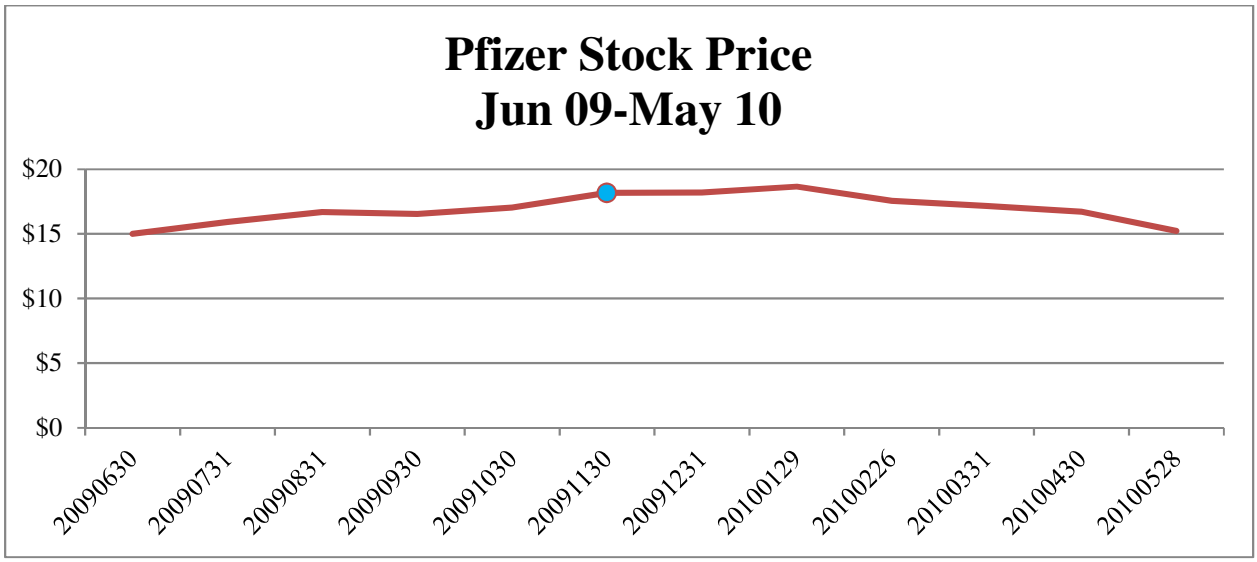
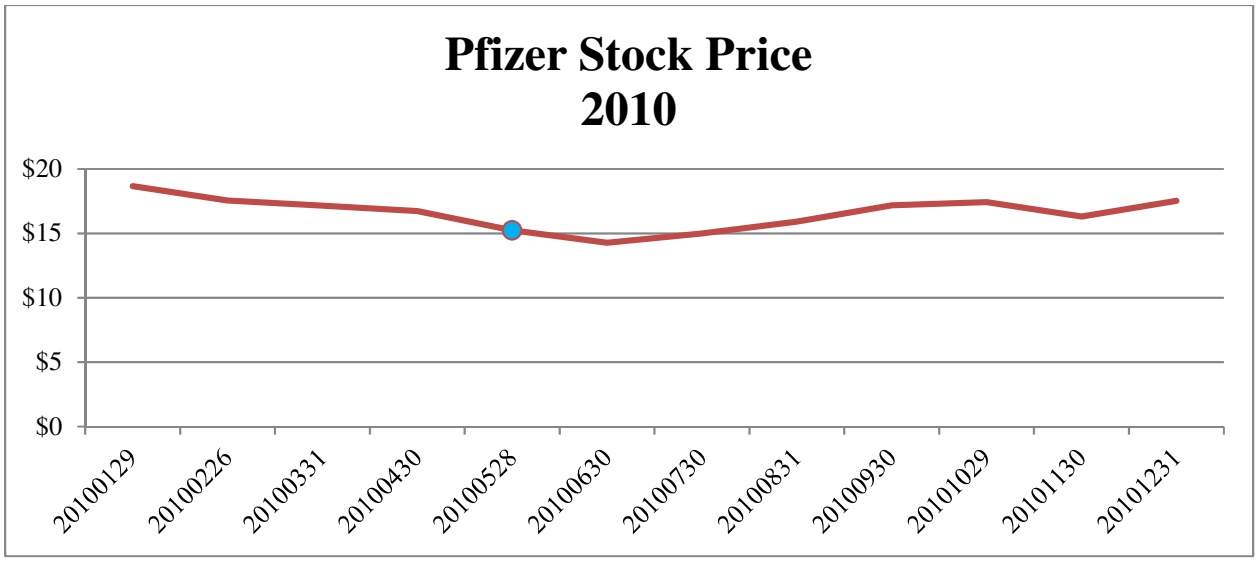
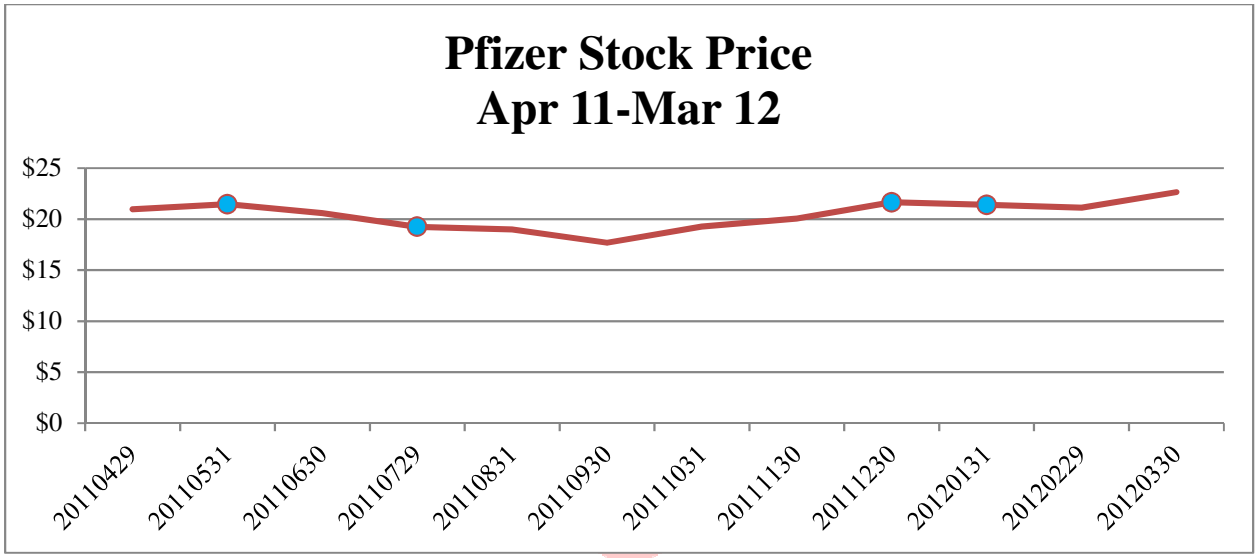
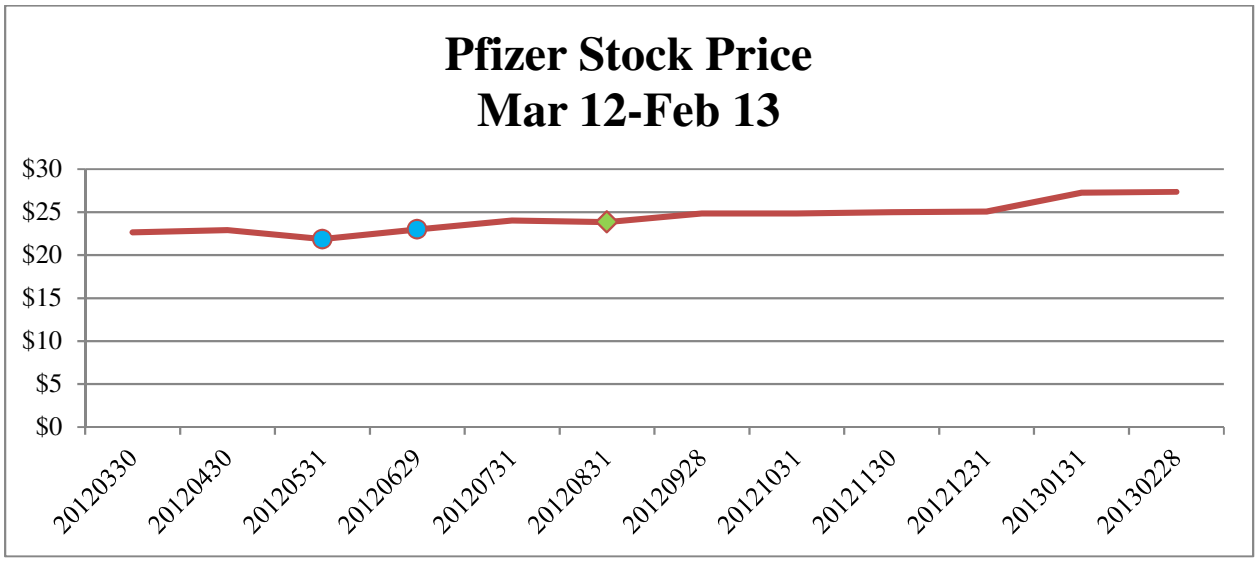
20060929
20061031

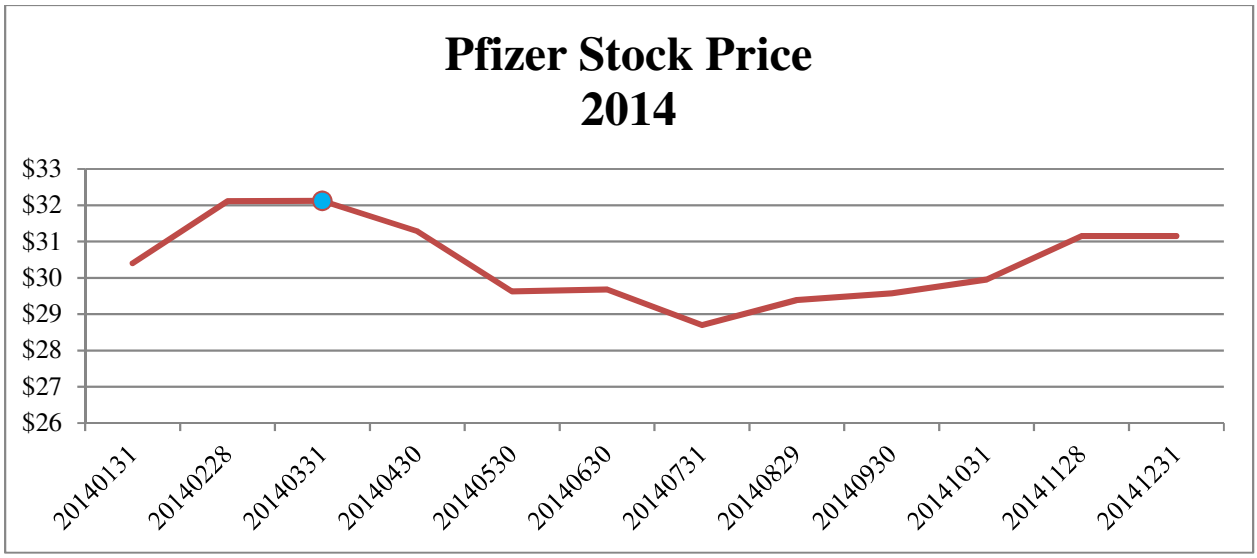

Pfizer Stock Price
May 08-Apr 09
$25
$20
$15
$10
$5
$0
20080530
20080630
20080731
20080829
20080930
20081031
20081128
20081231
20090130
20090227
20090331
20090430


Pfizer Stock Price
Jun 09-May 10
$20
$15
$10
$5
$0
20090630
20090731
20090831
20090930
20091030
20091130
20091231
20100129
20100226
20100331
20100430
20100528

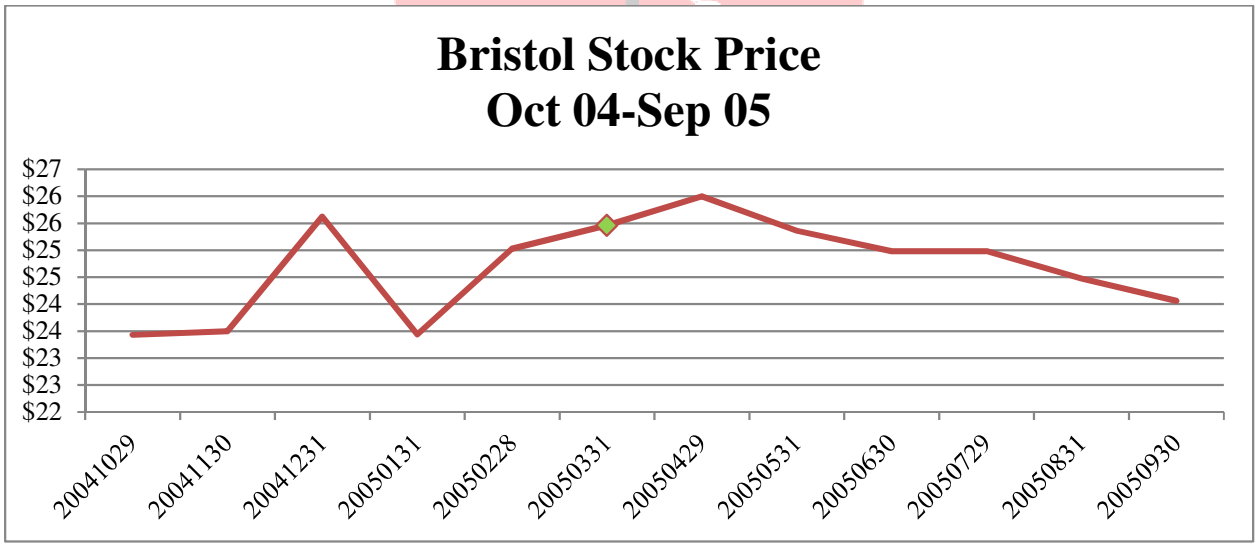

Pfizer Stock Price
2010
$20
$15
$10
$5
$0
20100129
20100226
20100331
20100430
20100528
20100630
20100730
20100831
20100930
20101029
20101130
20101231

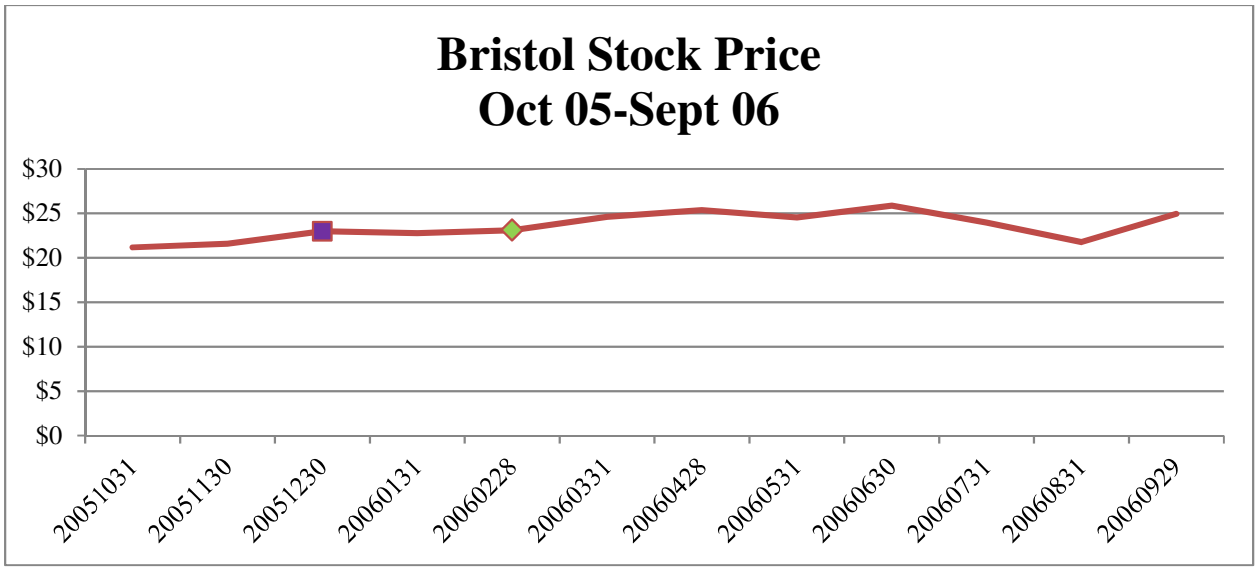

Pfizer Stock Price
Apr 11-Mar 12
$25
$20
$15
$10
$5
$0
20110429
20110531
20110630
20110729
20110831
20110930
20111031
20111130
20111230
20120131
20120229
20120330

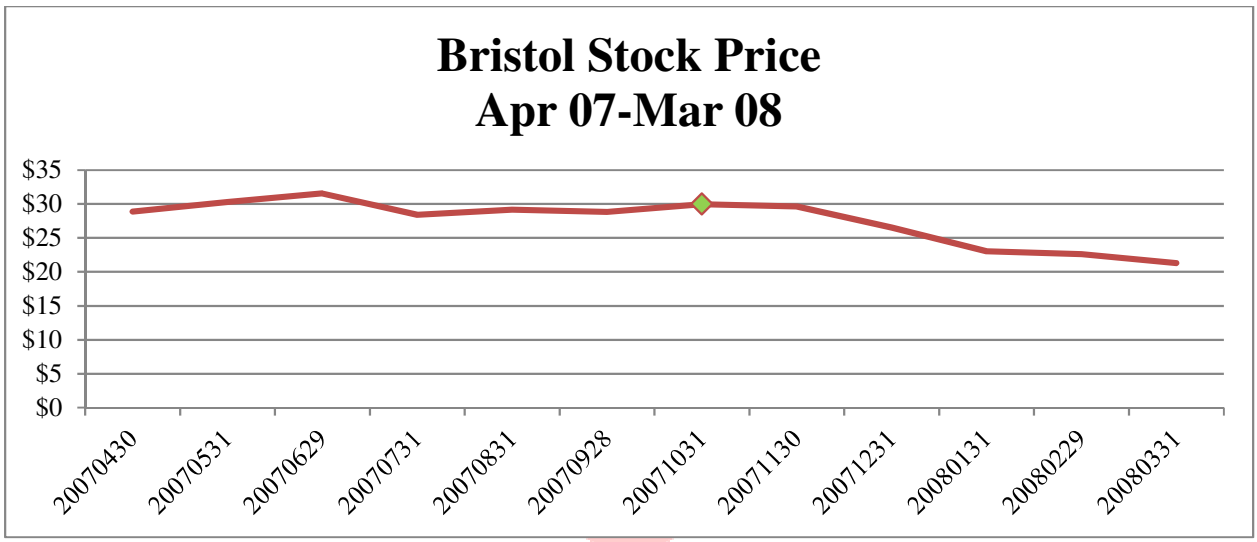

Pfizer Stock Price
Mar 12-Feb 13
$30
$25
$20
$15
$10
$5
$0
20120330
20120430
20120531
20120629
20120731
20120831
20120928
20121031
20121130
20121231
20130131
20130228

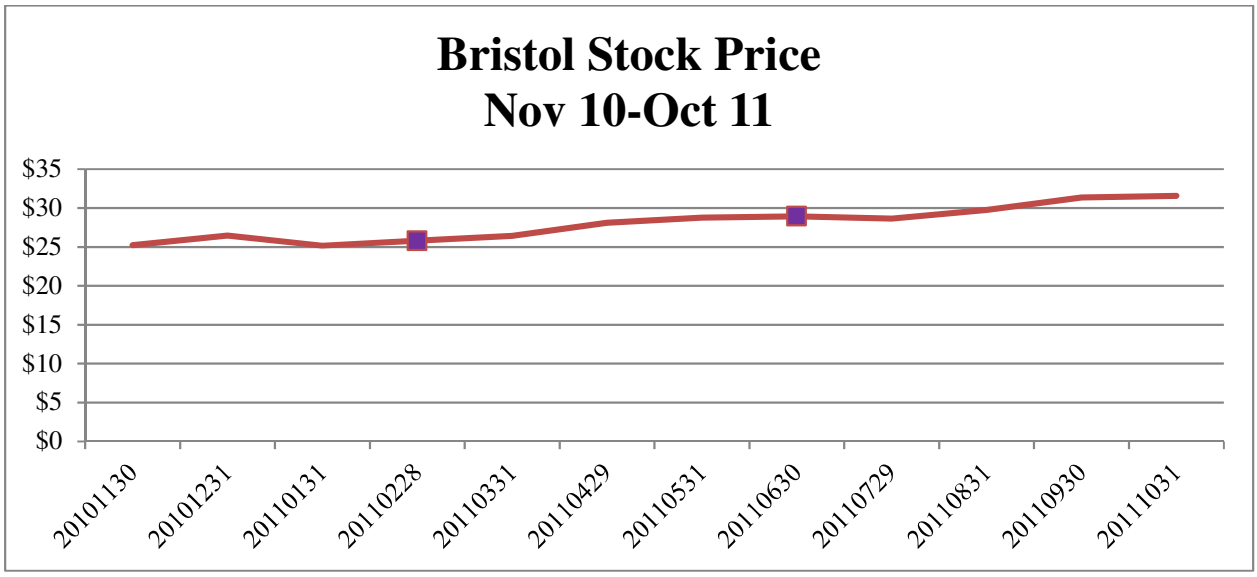


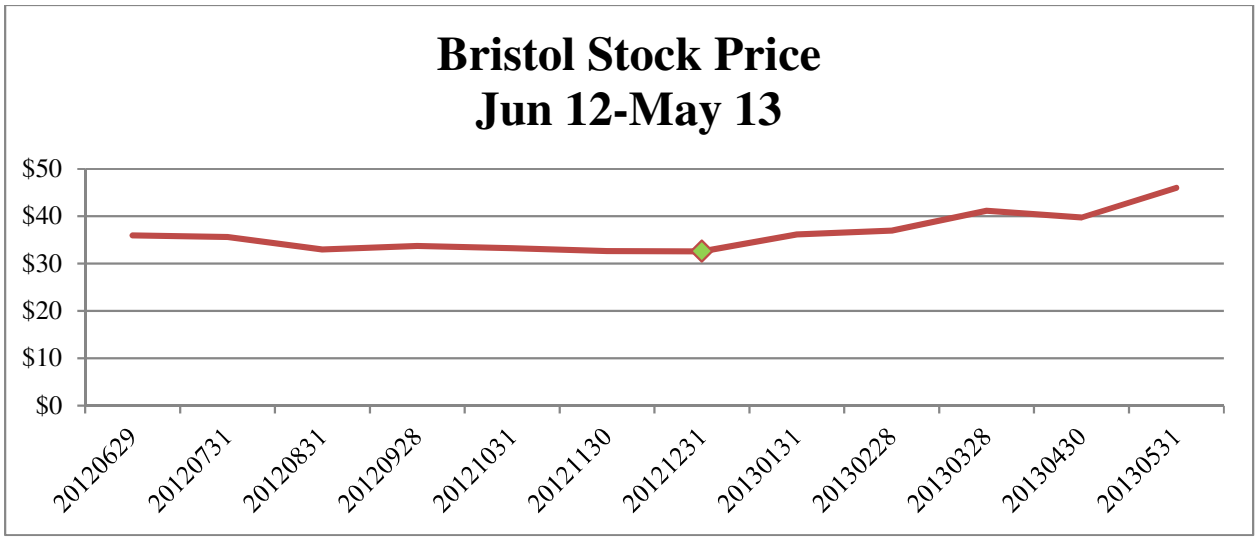
1.3 Bristol-Myers Squibb's Stock price change based on the drug approval data from Table 1 above

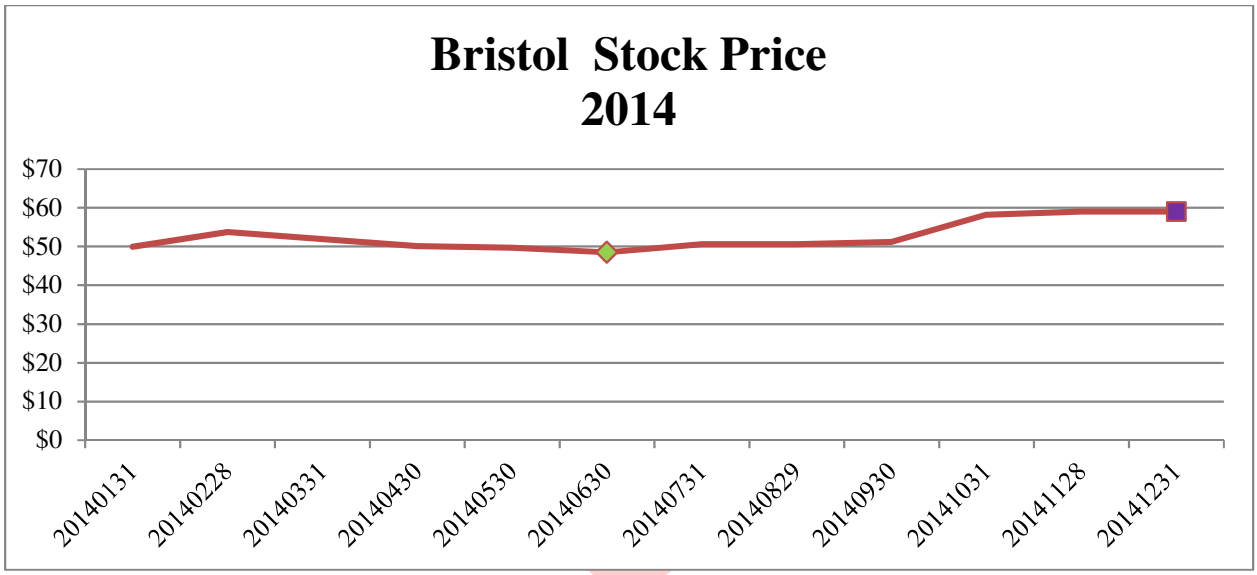



Bristol Stock Price
Oct 05-Sept 06
$30
$25
$20
$15
$10
$5
$0
20051031
20051130
20051230
20060131
20060228
20060331
20060428
20060531
20060630
20060731
20060831
20060929

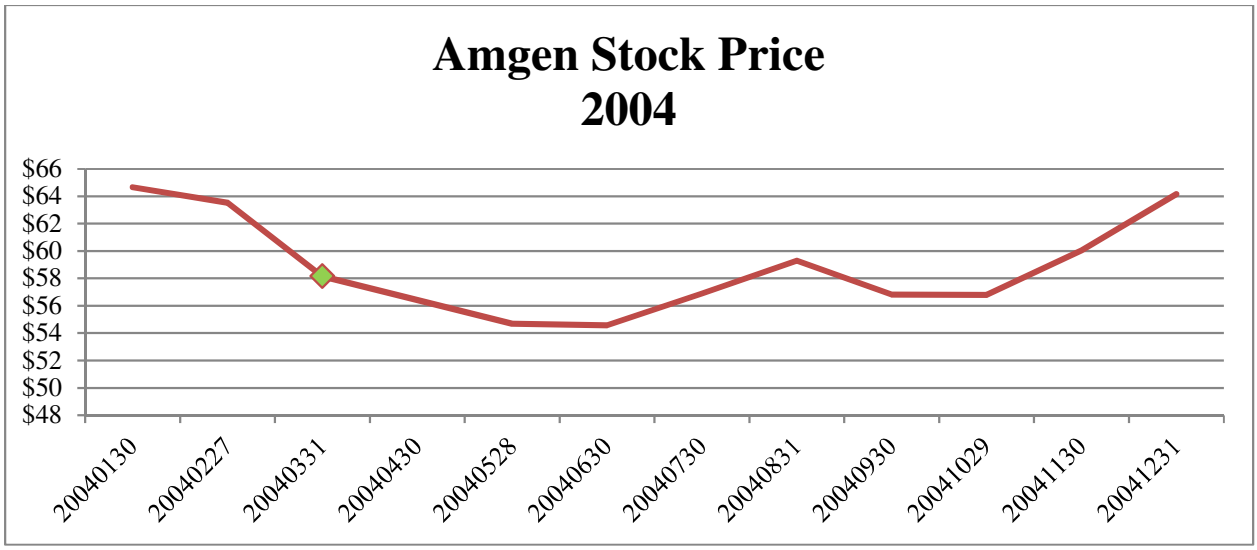

Bristol Stock Price
Apr 07-Mar 08
$35
$30
$25
$20
$15
$10
$5
$0
20070430
20070531
20070629
20070731
20070831
20070928
20071031
20071130
20071231
20080131
20080229
20080331

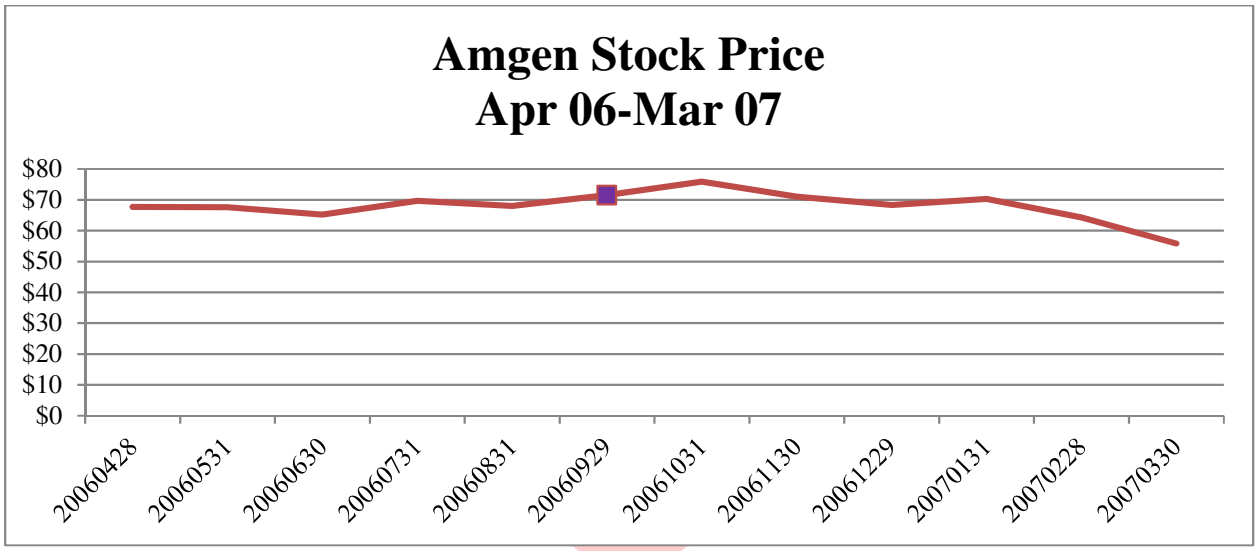

Bristol Stock Price
Nov 10-Oct 11
$35
$30
$25
$20
$15
$10
$5
$0
20101130
20101231
20110131
20110228
20110331
20110429
20110531
20110630
20110729
20110831
20110930
20111031

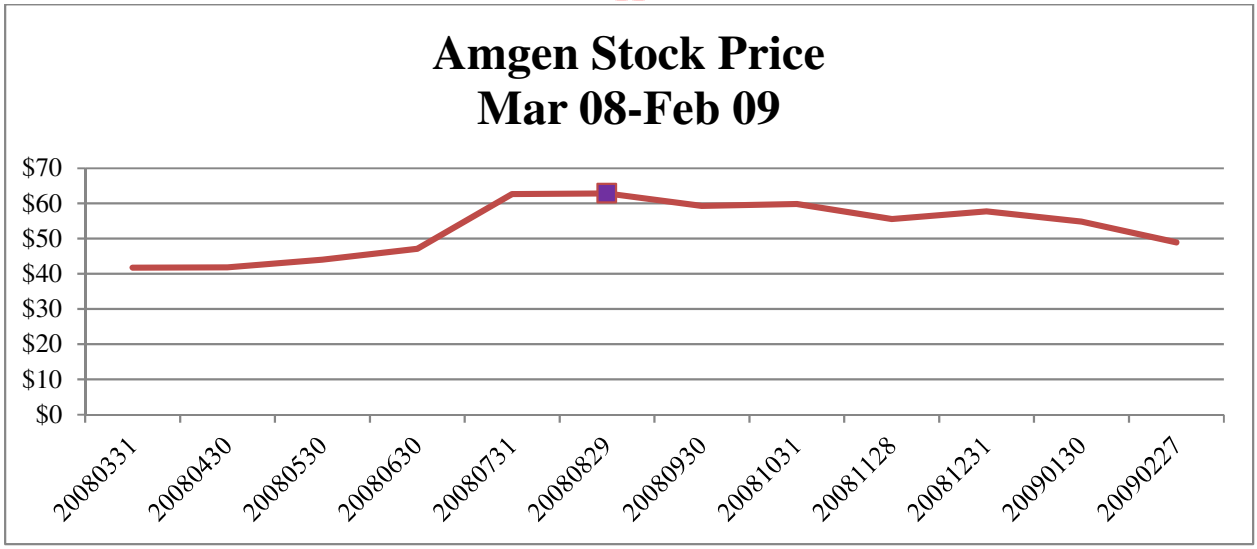


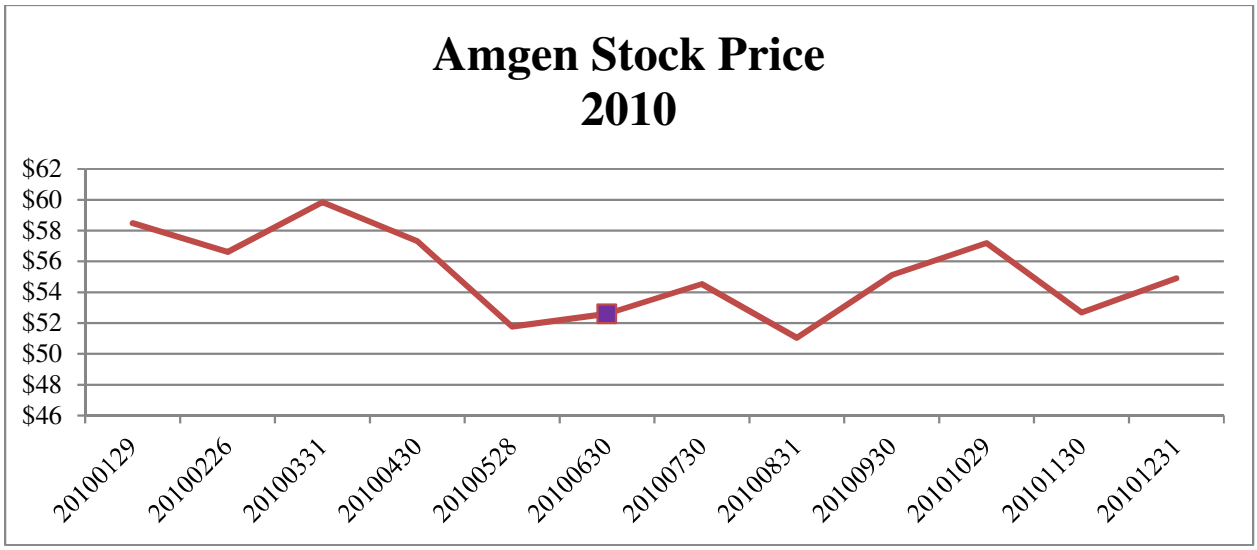


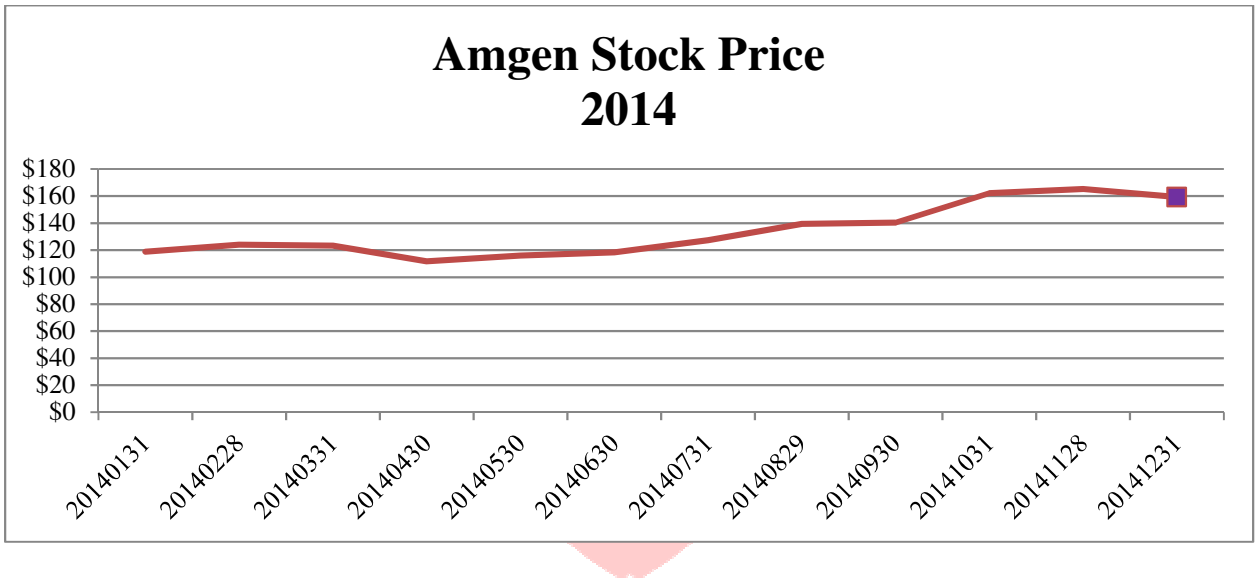
1.4 Amgen's Stock price change based on the drug approval data from Table 1 above


Amgen Stock Price
2004
$66
$64
$62
$60
$58
$56
$54
$52
$50
$48
20040130
20040227
20040331
20040430
20040528
20040630
20040730
20040831
20040930
20041029
20041130
20041231

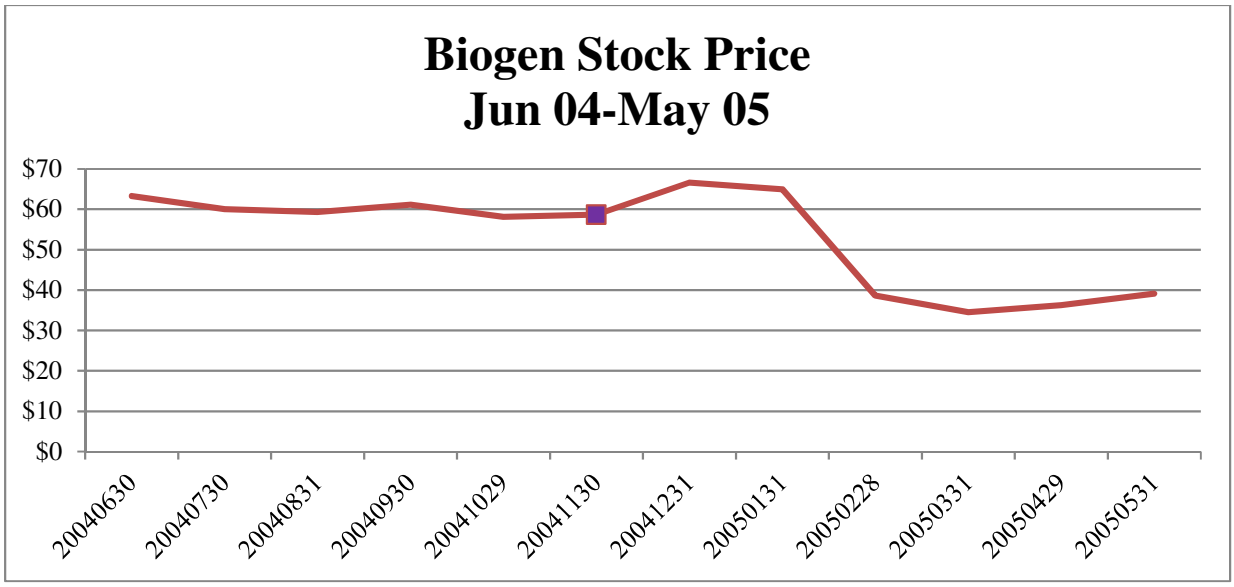

Amgen Stock Price
Apr 06-Mar 07
$80
$70
$60
$50
$40
$30
$20
$10
$0
20060428
20060531
20060630
20060731
20060831
20060929
20061031
20061130
20061229
20070131
20070228
20070330

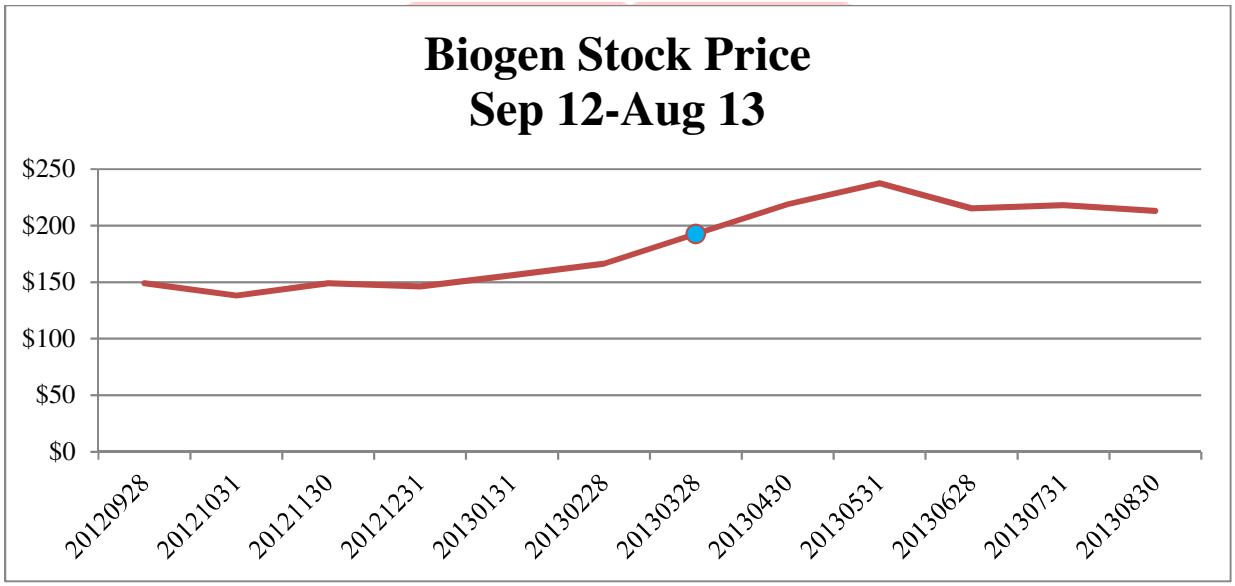

Amgen Stock Price
Mar 08-Feb 09
$70
$60
$50
$40
$30
$20
$10
$0
20080331
20080430
20080530
20080630
20080731
20080829
20080930
20081031
20081128
20081231
20090130
20090227

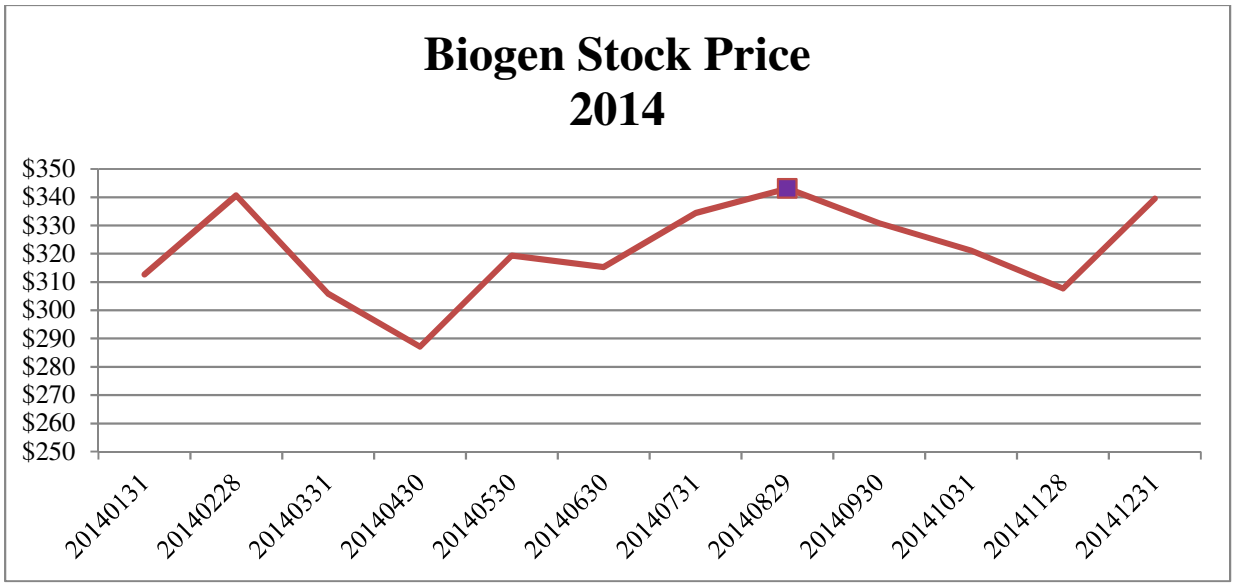




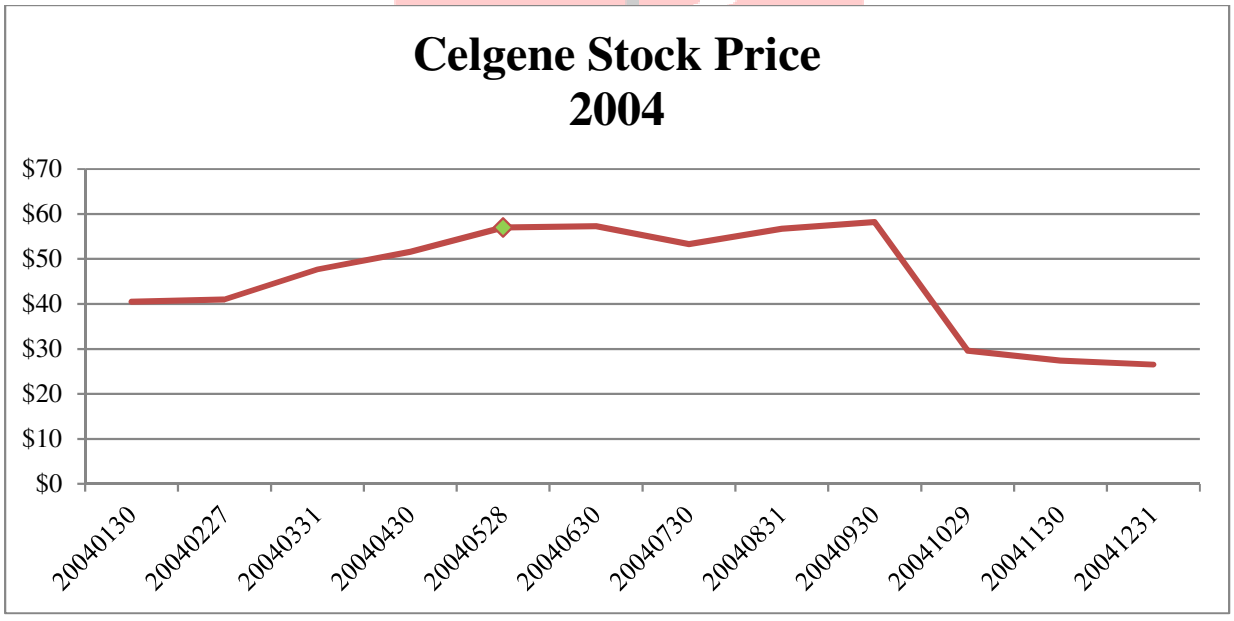
1.5 Biogen's Stock price change based on the drug approval data from Table 1 above

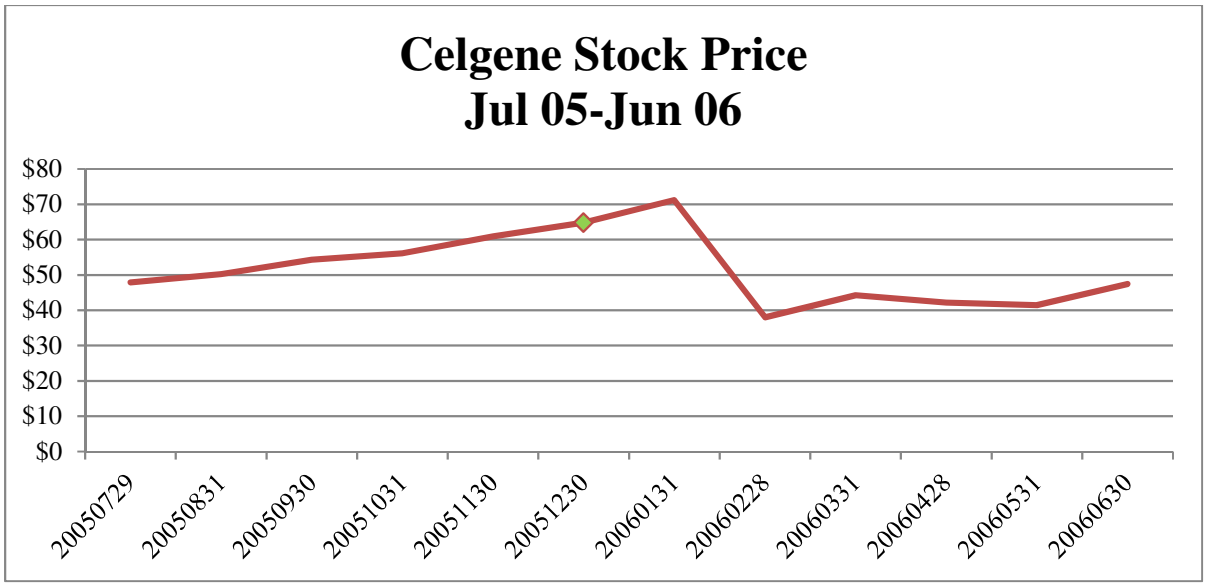

Biogen Stock Price
Jun 04-May 05
$70
$60
$50
$40
$30
$20
$10
$0
20040630
20040730
20040831
20040930
20041029
20041130
20041231
20050131
20050228
20050331
20050429
20050531

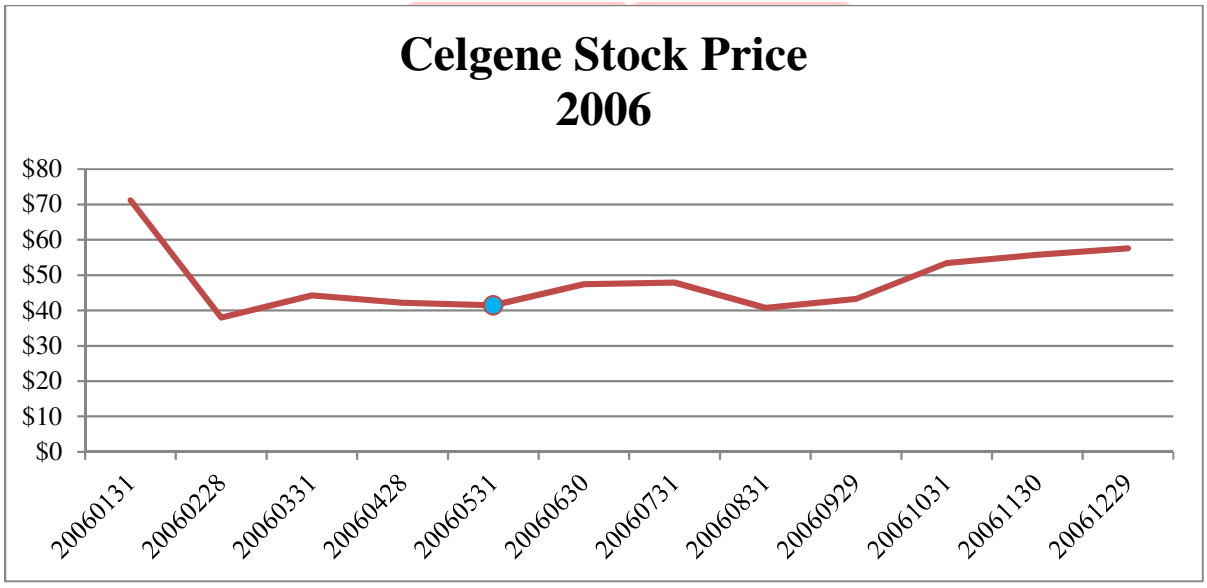

Biogen Stock Price
Sep 12-Aug 13
$250
$200
$150
$100
$50
$0
20120928
20121031
20121130
20121231
20130131
20130228
20130328
20130430
20130531
20130628
20130731
20130830

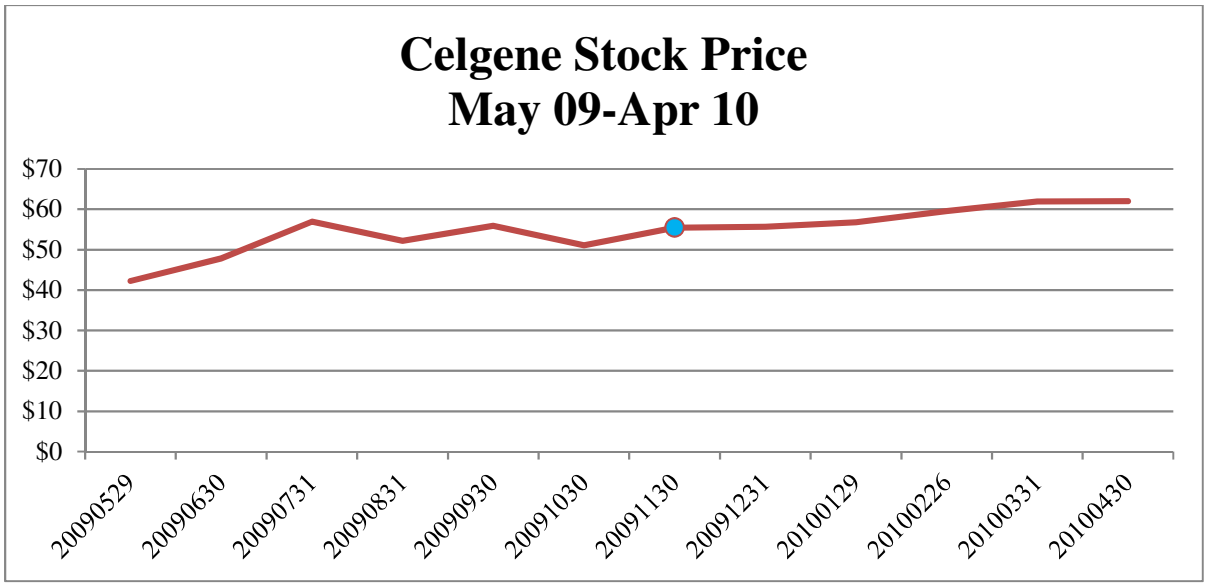


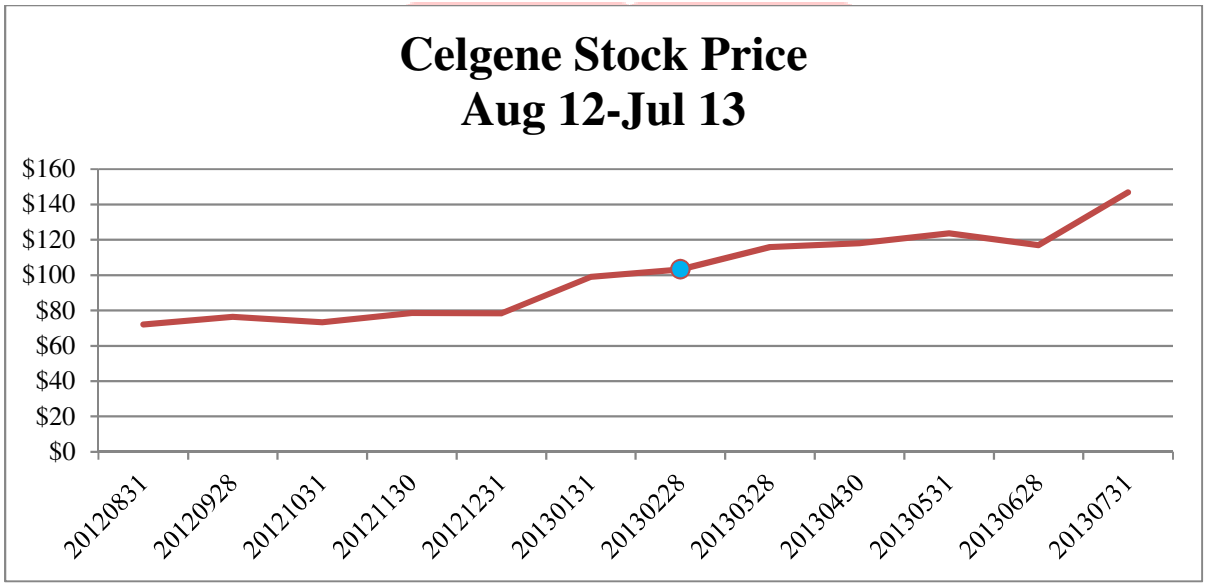
1.6 Celgene's Stock price change based on the drug approval data from Table 1 above

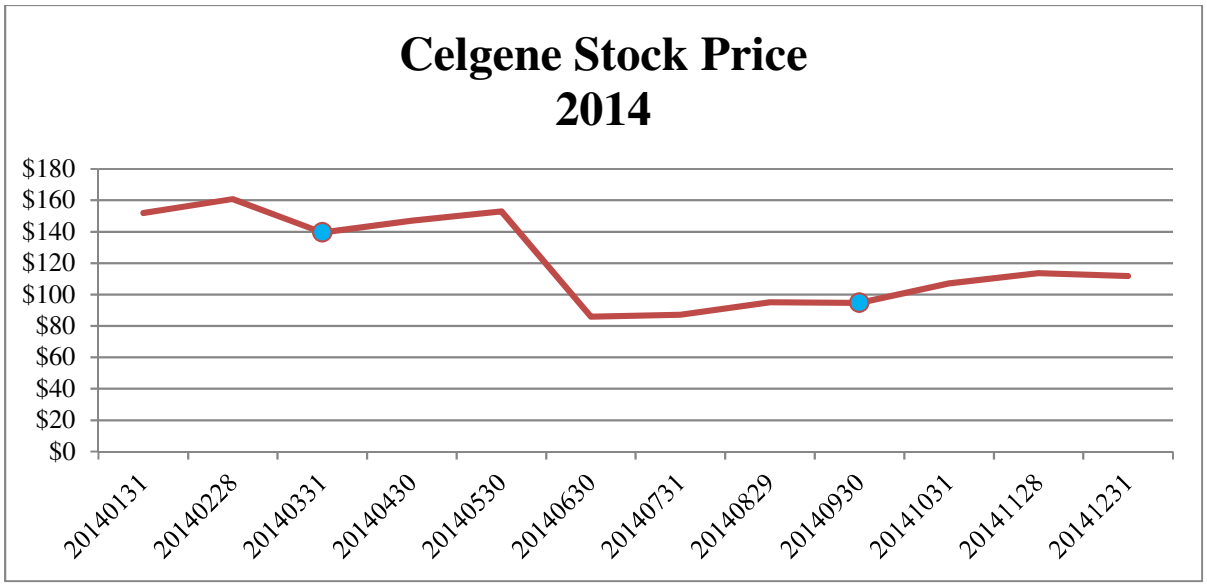



Celgene Stock Price
Jul 05-Jun 06
$80
$70
$60
$50
$40
$30
$20
$10
$0
20050729
20050831
20050930
20051031
20051130
20051230
20060131
20060228
20060331
20060428
20060531
20060630

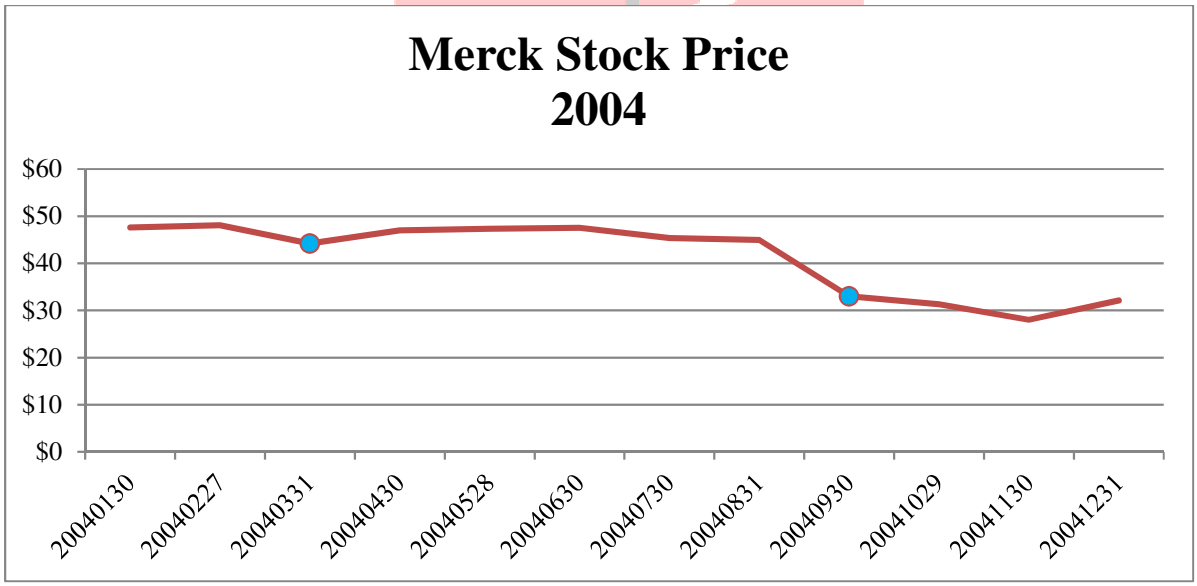

Celgene Stock Price
2006
$80
$70
$60
$50
$40
$30
$20
$10
$0
20060131
20060228
20060331
20060428
20060531
20060630
20060731
20060831
20060929
20061031
20061130
20061229

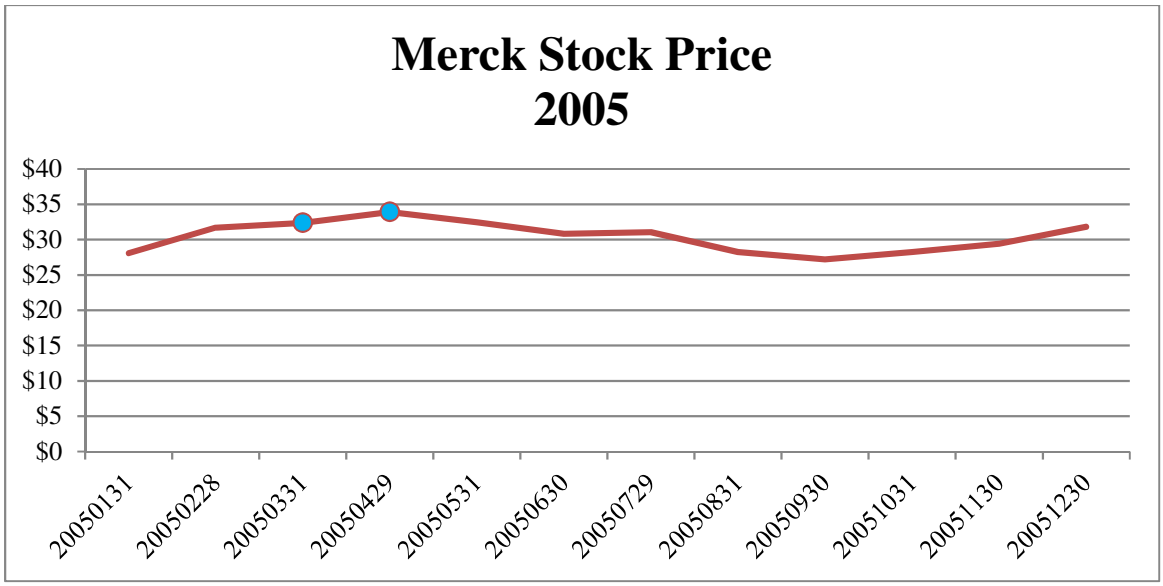

Celgene Stock Price
May 09-Apr 10
$70
$60
$50
$40
$30
$20
$10
$0
20090529
20090630
20090731
20090831
20090930
20091030
20091130
20091231
20100129
20100226
20100331
20100430

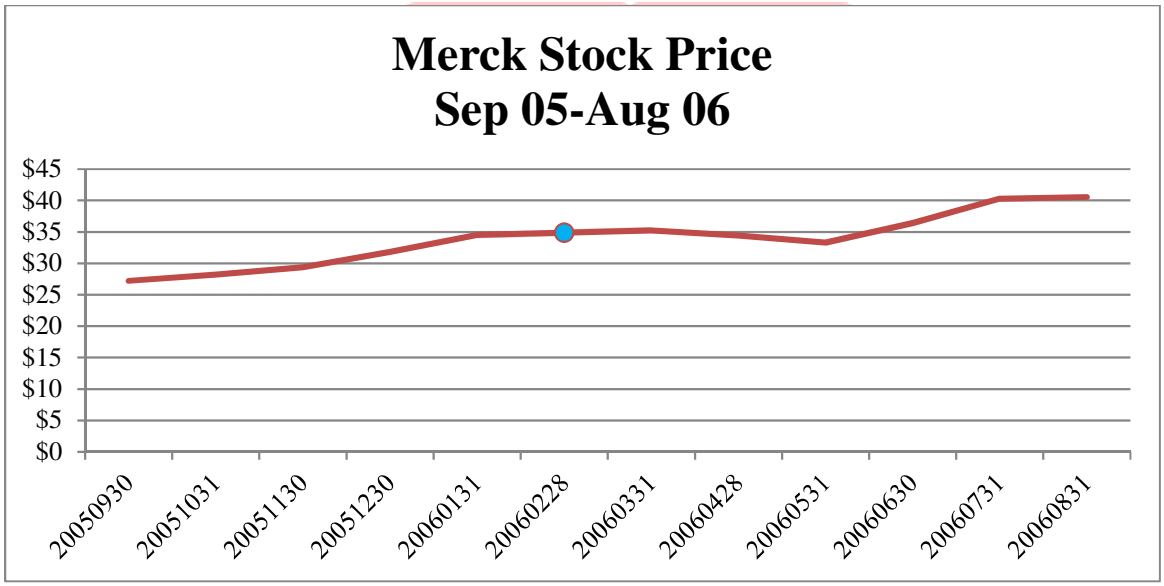

Celgene Stock Price
Aug 12-Jul 13
$160
$140
$120
$100
$80
$60
$40
$20
$0
20120831
20120928
20121031
20121130
20121231
20130131
20130228
20130328
20130430
20130531
20130628
20130731

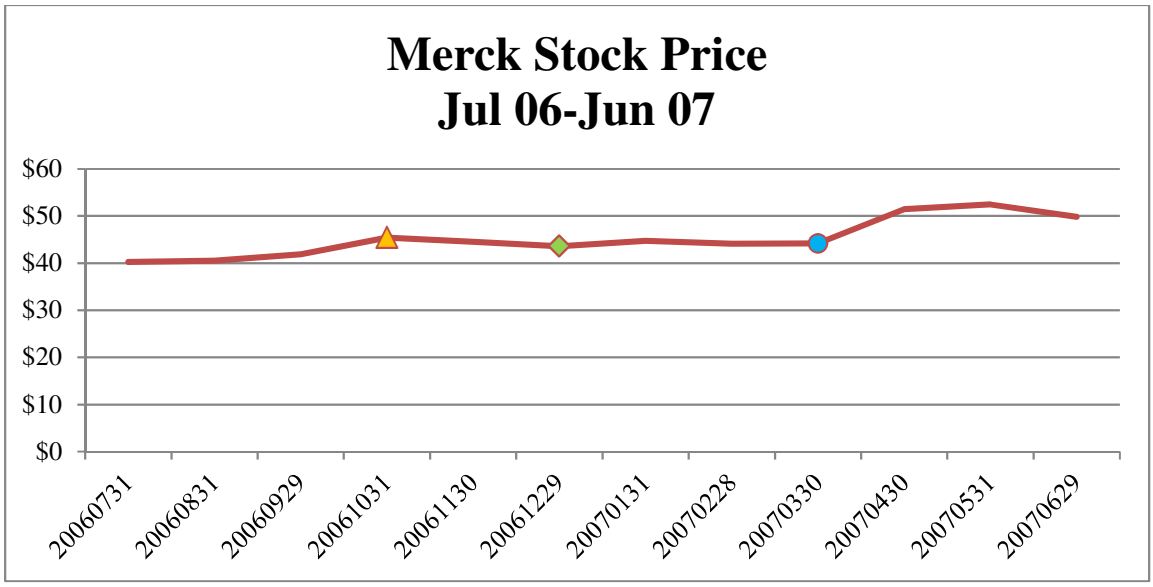


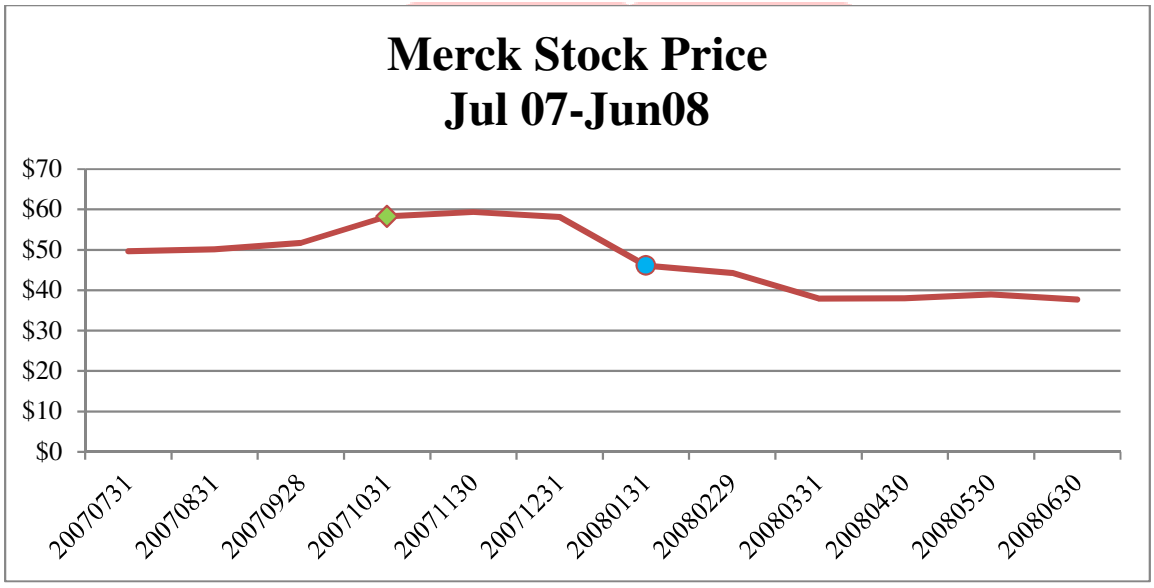
1.7 Merck's Stock price change based on the drug approval data from Table 1 above

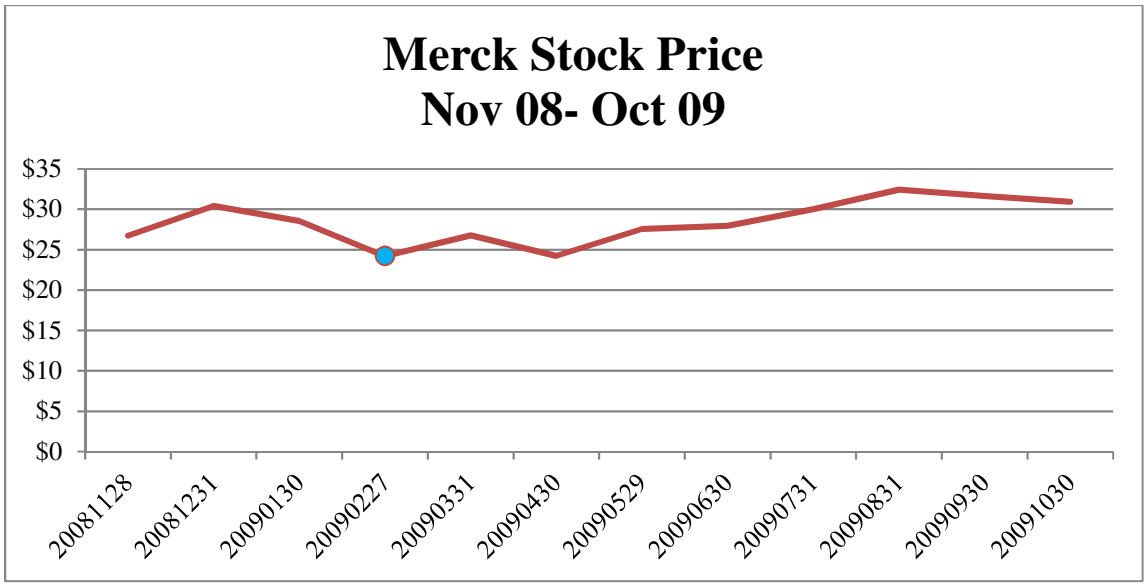


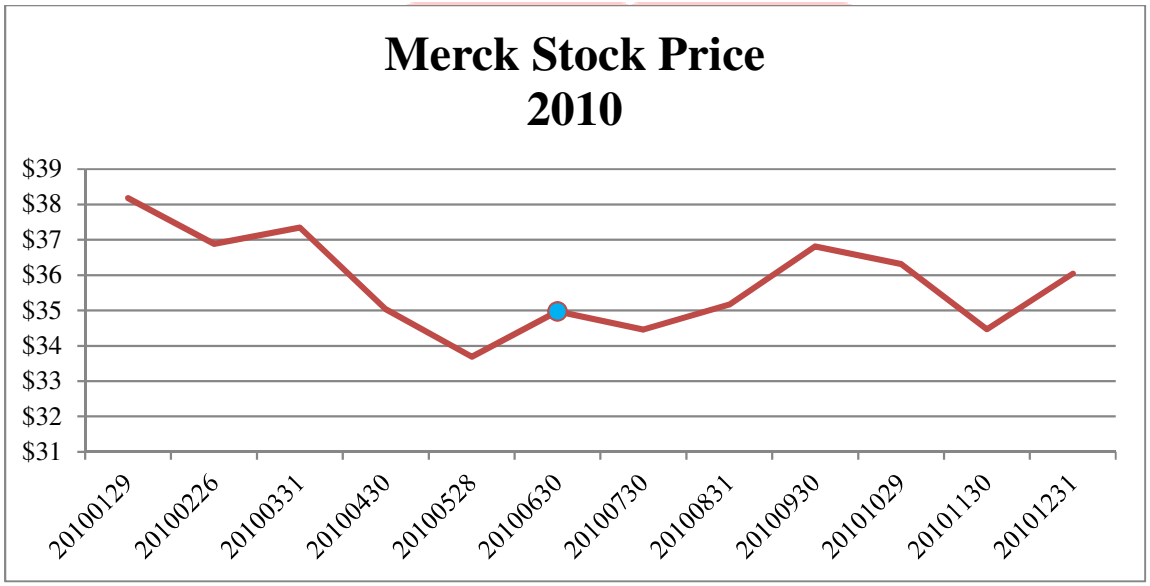

Merck Stock Price
2005
$40
$35
$30
$25
$20
$15
$10
$5
$0
20050131
20050228
20050331
20050429
20050531
20050630
20050729
20050831
20050930
20051031
20051130
20051230

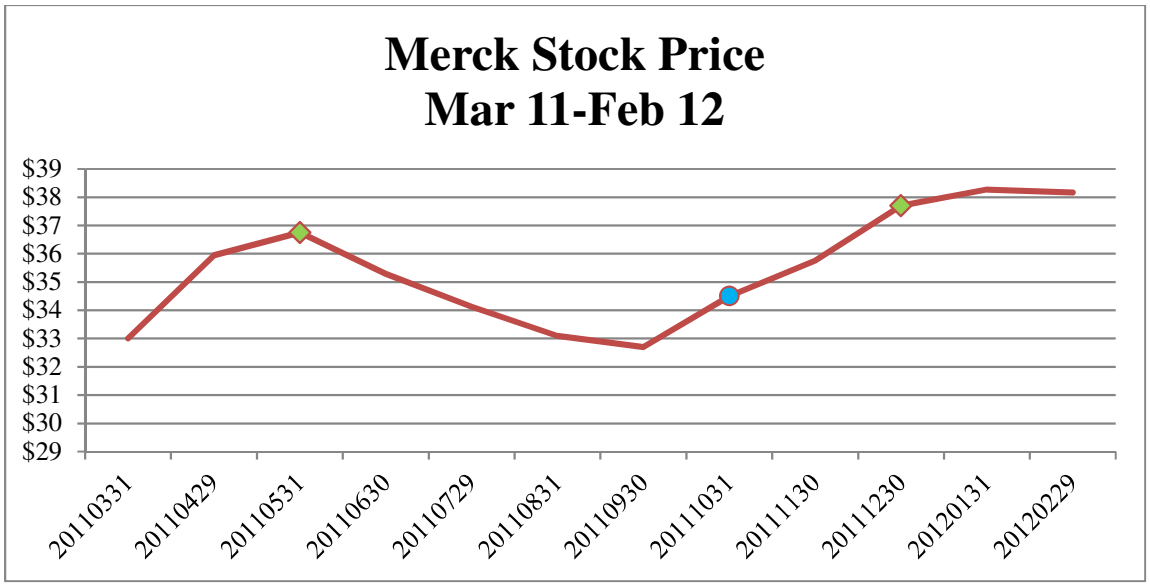

Merck Stock Price
Sep 05-Aug 06
$45
$40
$35
$30
$25
$20
$15
$10
$5
$0
20050930
20051031
20051130
20051230
20060131
20060228
20060331
20060428
20060531
20060630
20060731
20060831

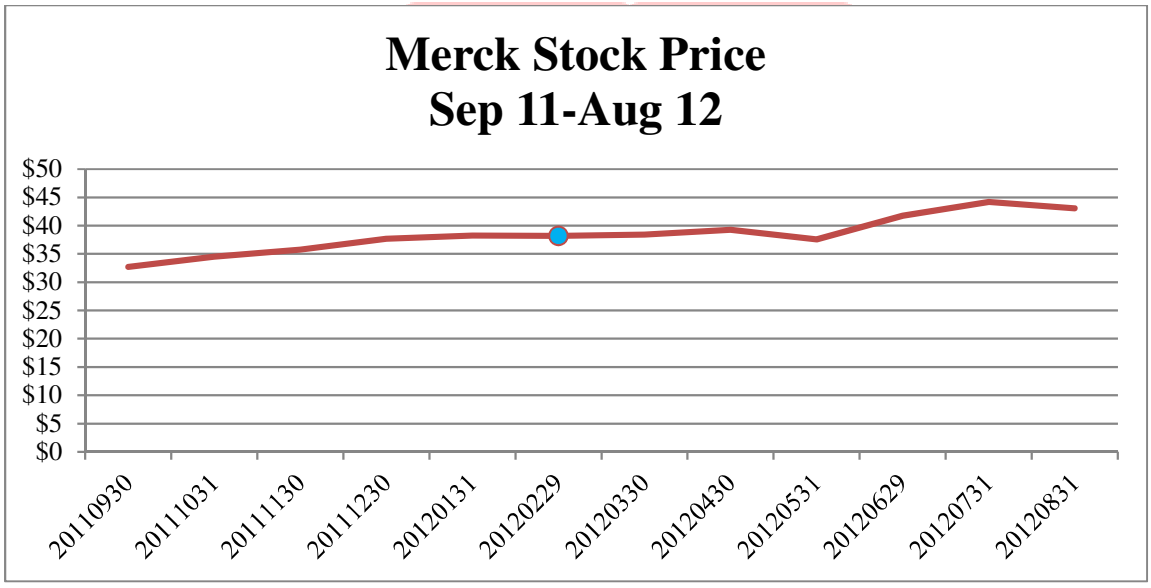

Merck Stock Price
Jul 06-Jun 07
$60
$50
$40
$30
$20
$10
$0
20060731
20060831
20060929
20061031
20061130
20061229
20070131
20070228
20070330
20070430
20070531
20070629

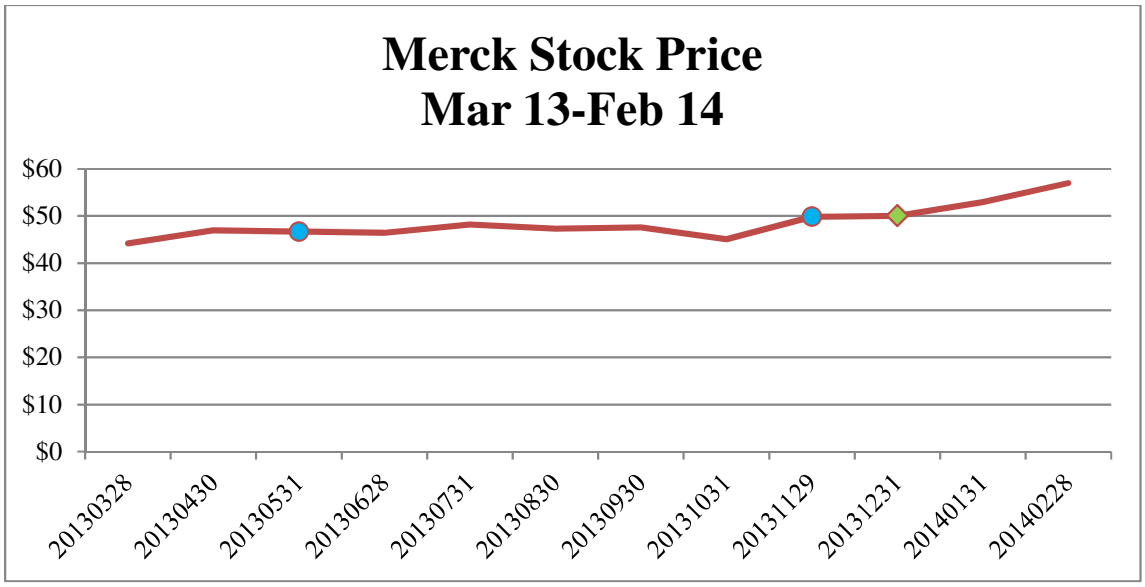

Merck Stock Price
Jul 07-Jun08
$70
$60
$50
$40
$30
$20
$10
$0
20070731
20070831
20070928
20071031
20071130
20071231
20080131
20080229
20080331
20080430
20080530
20080630

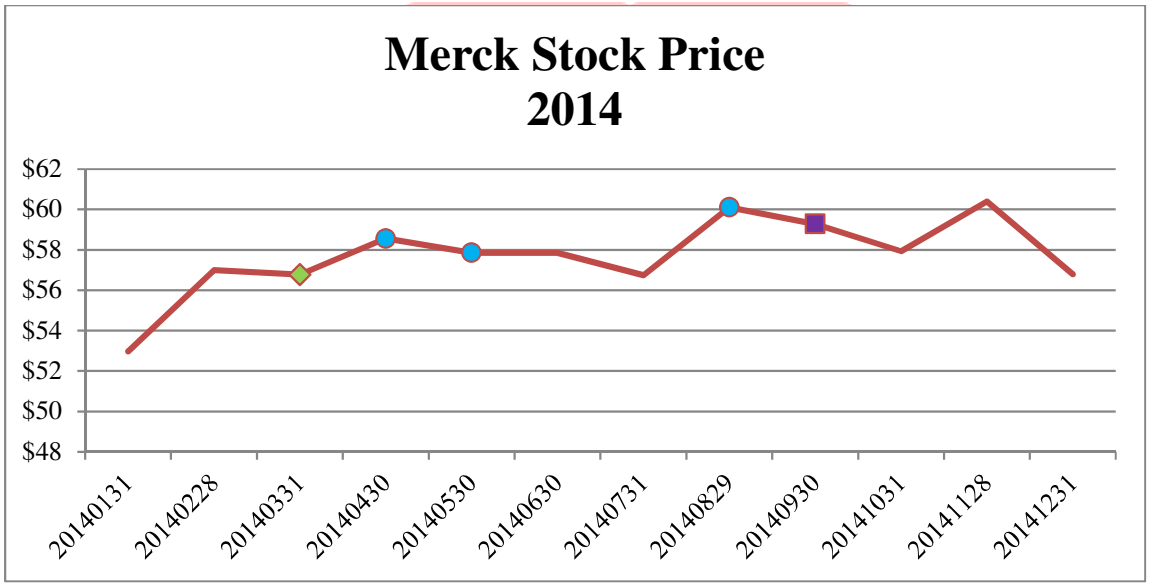

Merck Stock Price
Nov 08- Oct 09
$35
$30
$25
$20
$15
$10
$5
$0
20081128
20081231
20090130
20090227
20090331
20090430
20090529
20090630
20090731
20090831
20090930
20091030


Merck Stock Price
2010
$39
$38
$37
$36
$35
$34
$33
$32
$31
20100129
20100226
20100331
20100430
20100528
20100630
20100730
20100831
20100930
20101029
20101130
20101231

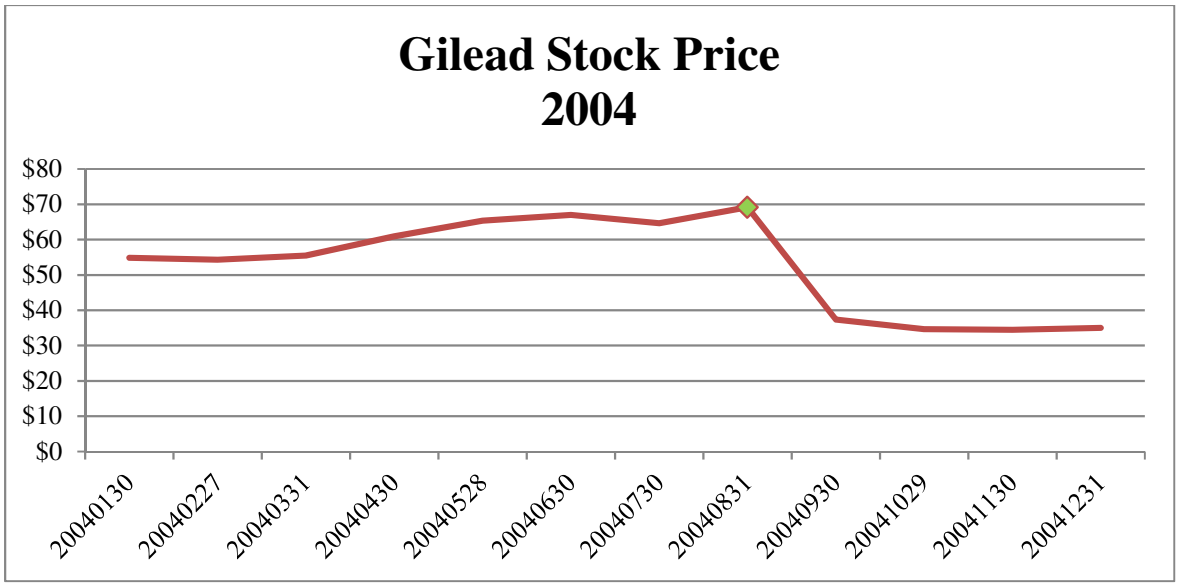

Merck Stock Price
Mar 11-Feb 12
$39
$38
$37
$36
$35
$34
$33
$32
$31
$30
$29
20110331
20110429
20110531
20110630
20110729
20110831
20110930
20111031
20111130
20111230
20120131
20120229

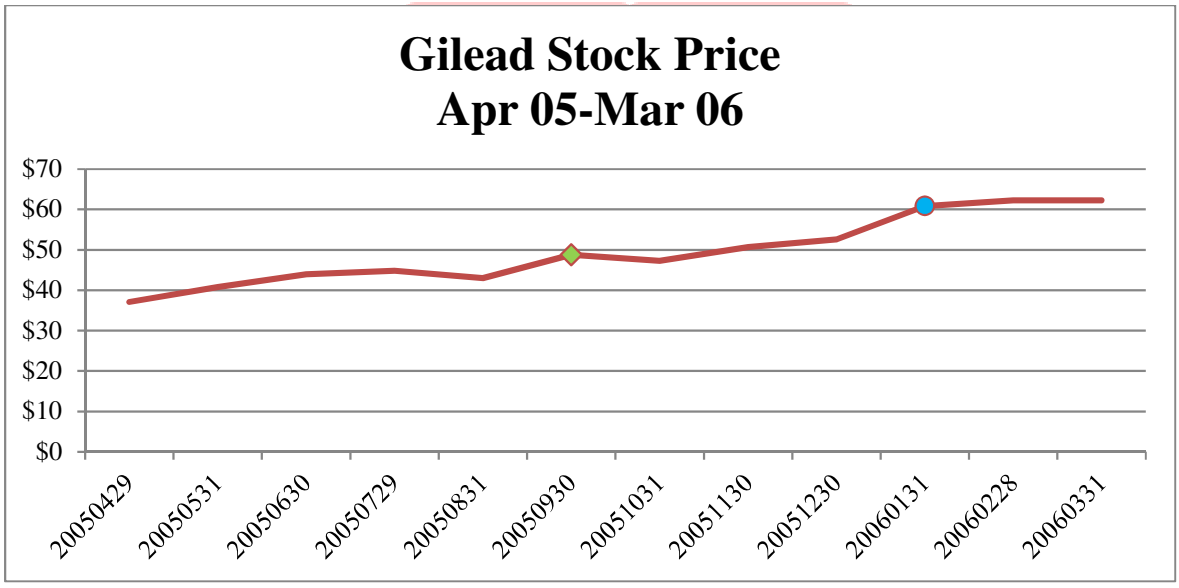

Merck Stock Price
Sep 11-Aug 12
$50
$45
$40
$35
$30
$25
$20
$15
$10
$5
$0
20110930
20111031
20111130
20111230
20120131
20120229
20120330
20120430
20120531
20120629
20120731
20120831

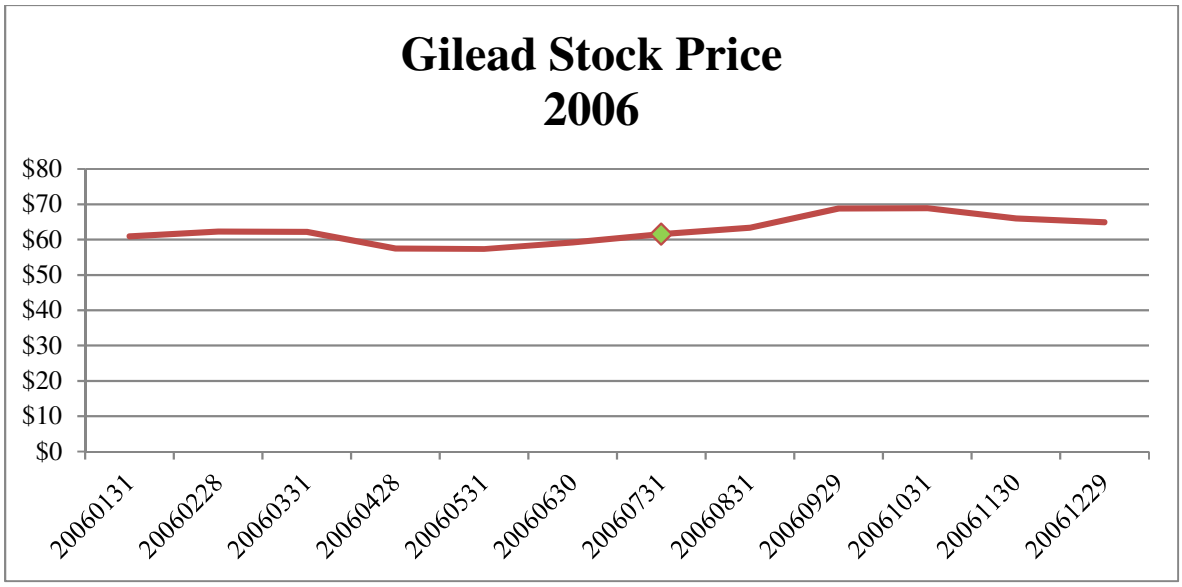


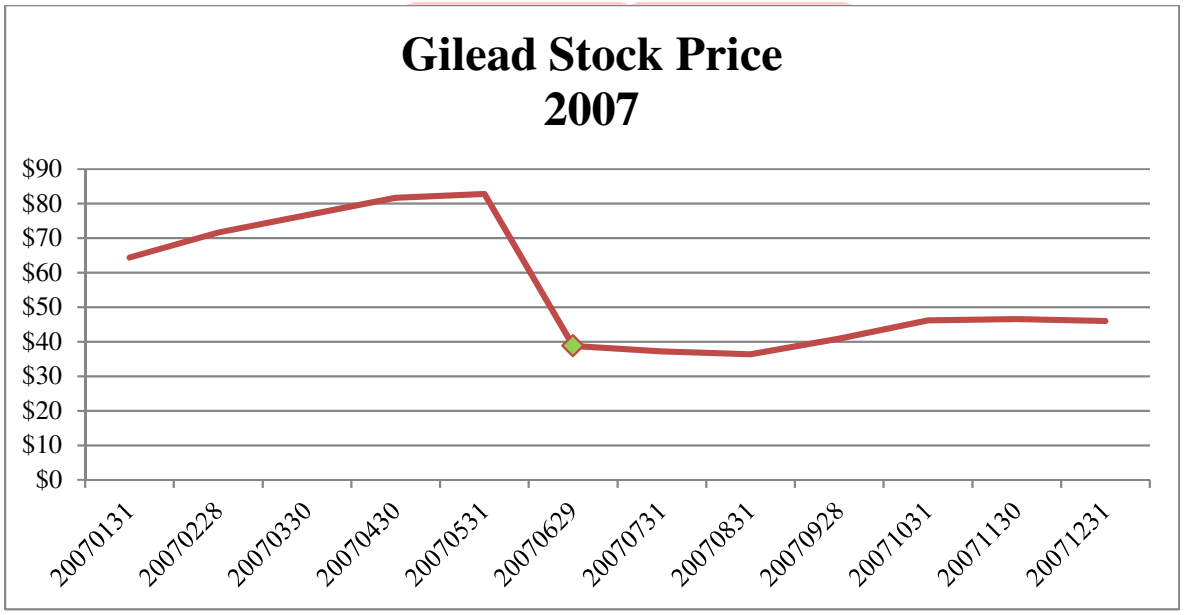


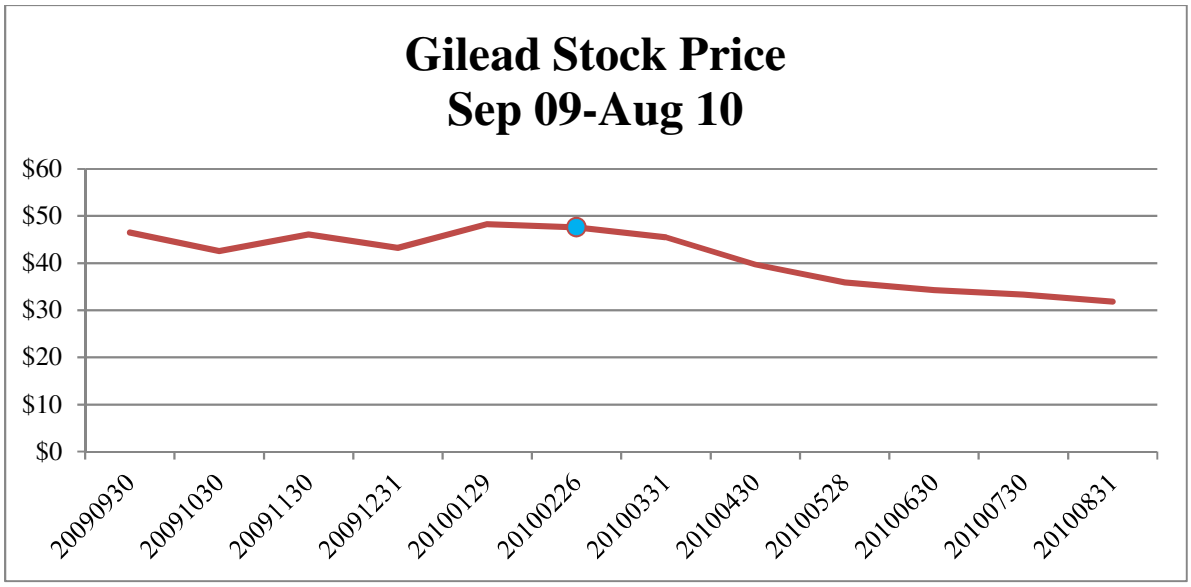
1.8 Gilead's Stock price change based on the drug approval data from Table 1 above

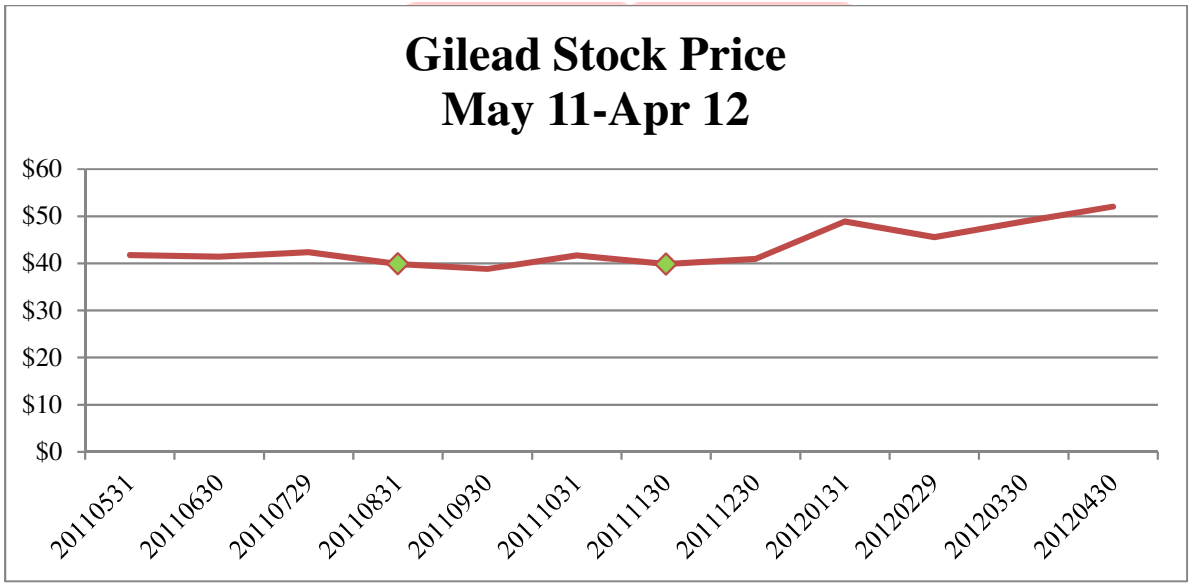

Gilead Stock Price
2004
$80
$70
$60
$50
$40
$30
$20
$10
$0
20040130
20040227
20040331
20040430
20040528
20040630
20040730
20040831
20040930
20041029
20041130
20041231

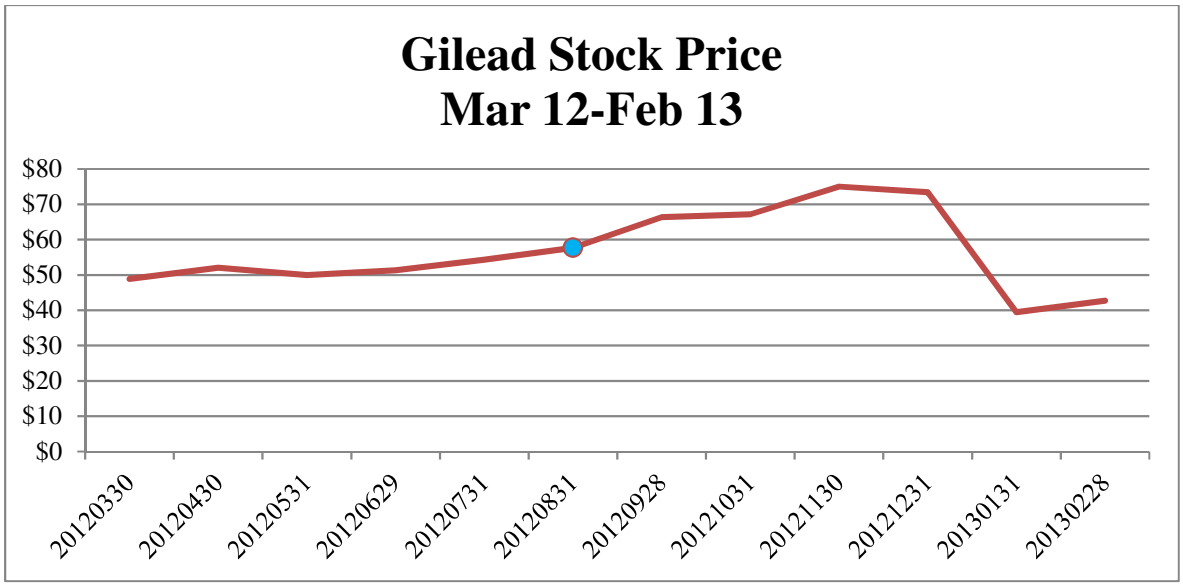

Gilead Stock Price
Apr 05-Mar 06
$70
$60
$50
$40
$30
$20
$10
$0
20050429
20050531
20050630
20050729
20050831
20050930
20051031
20051130
20051230
20060131
20060228
20060331

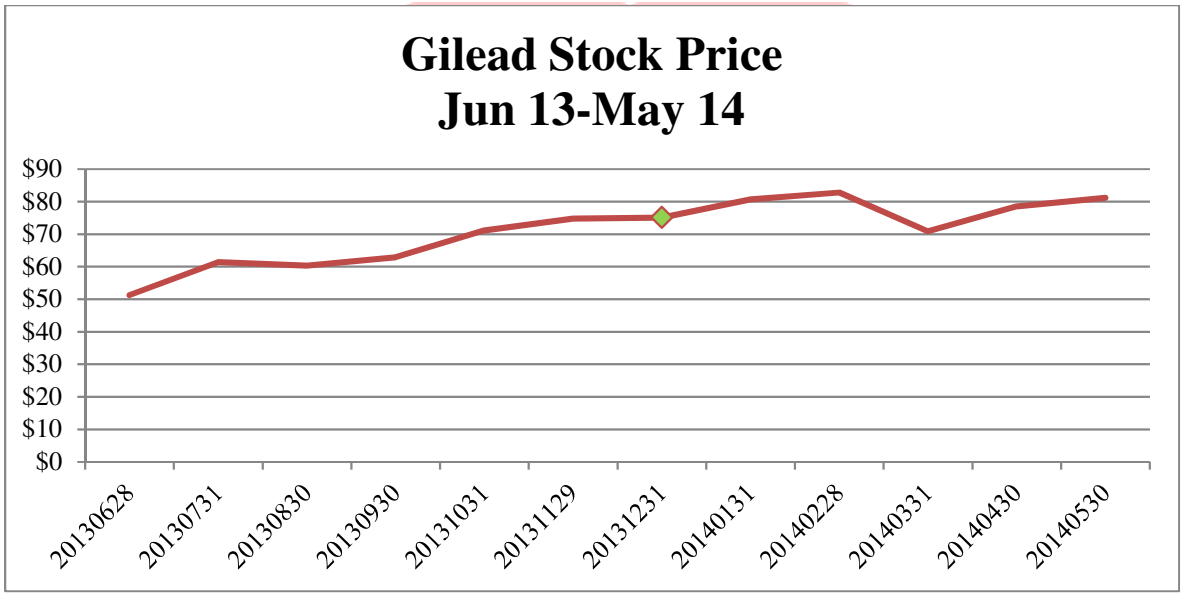

Gilead Stock Price
2006
$80
$70
$60
$50
$40
$30
$20
$10
$0
20060131
20060228
20060331
20060428
20060531
20060630
20060731
20060831
20060929
20061031
20061130
20061229

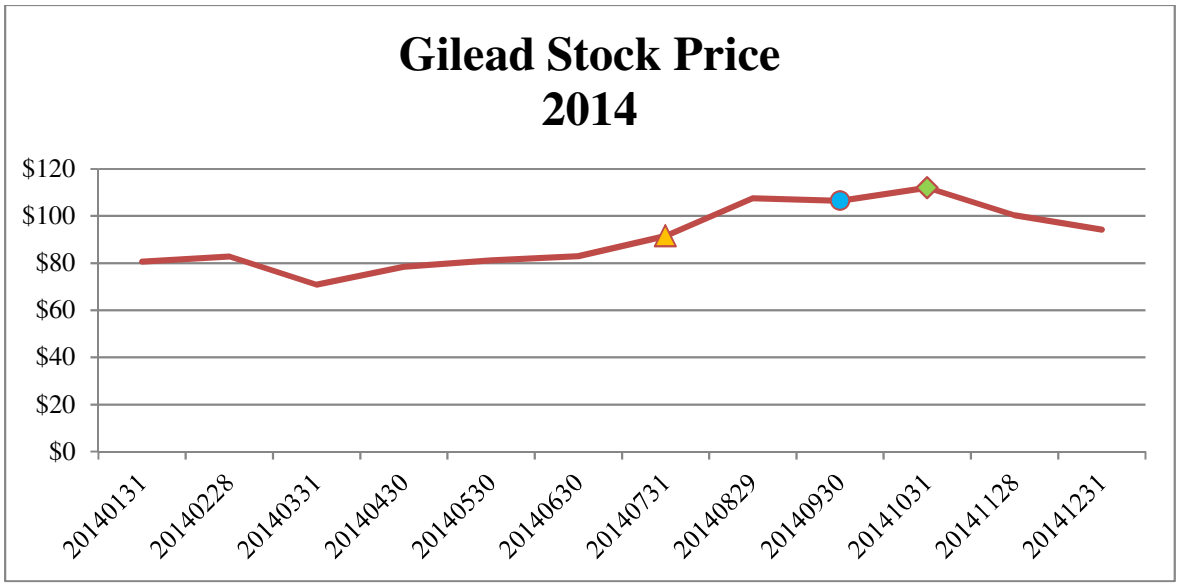

Gilead Stock Price
2007
$90
$80
$70
$60
$50
$40
$30
$20
$10
$0
20070131
20070228
20070330
20070430
20070531
20070629
20070731
20070831
20070928
20071031
20071130
20071231


Gilead Stock Price
Sep 09-Aug 10
$60
$50
$40
$30
$20
$10
$0
20090930
20091030
20091130
20091231
20100129
20100226
20100331
20100430
20100528
20100630
20100730
20100831

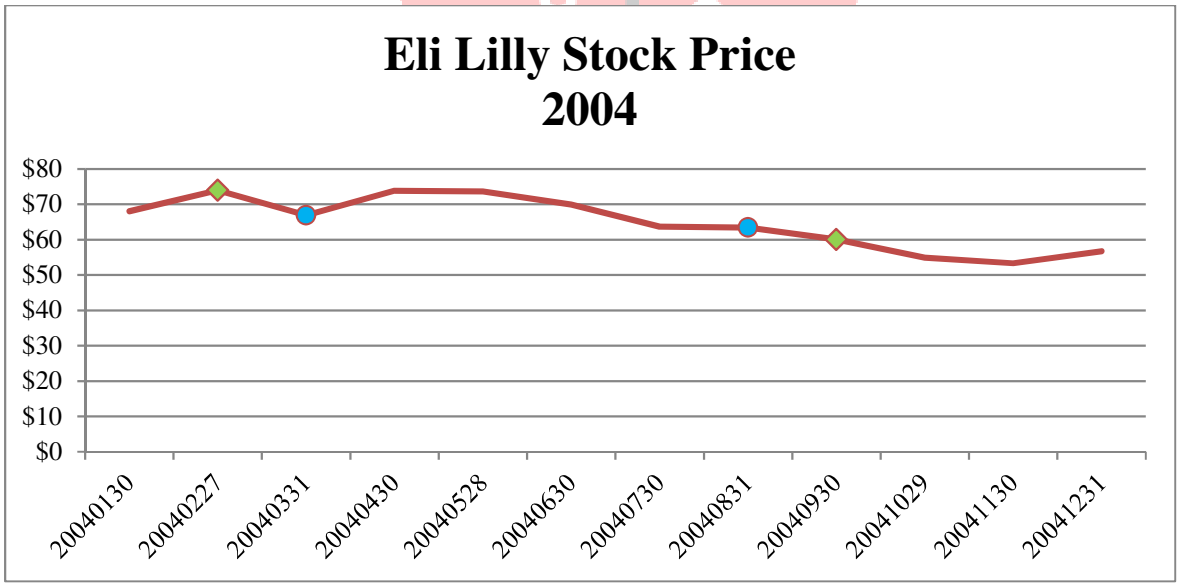

Gilead Stock Price
May 11-Apr 12
$60
$50
$40
$30
$20
$10
$0
20110531
20110630
20110729
20110831
20110930
20111031
20111130
20111230
20120131
20120229
20120330
20120430

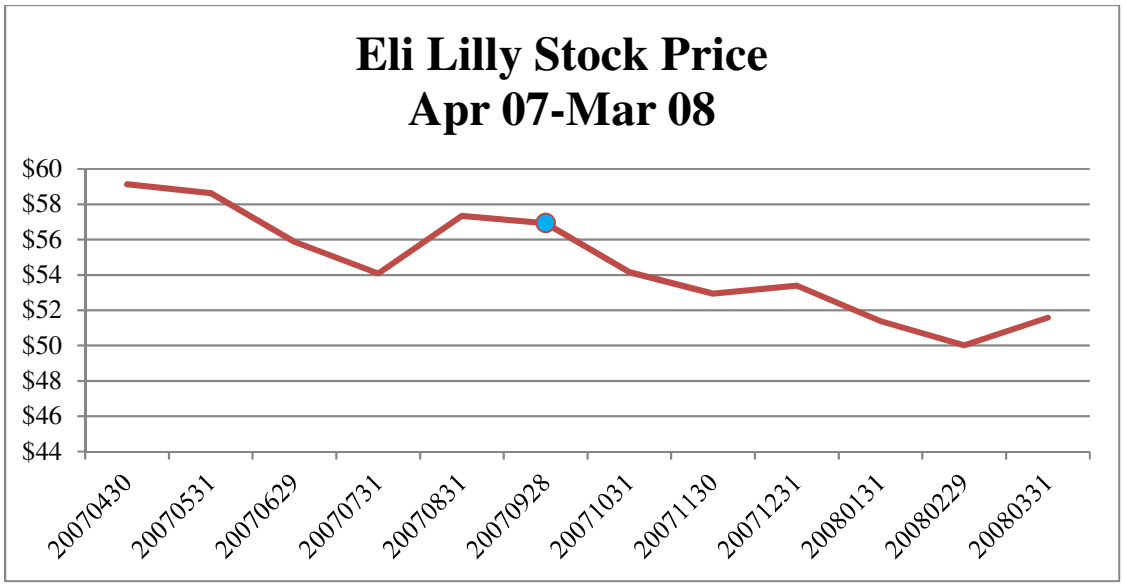

Gilead Stock Price
Mar 12-Feb 13
$80
$70
$60
$50
$40
$30
$20
$10
$0
20120330
20120430
20120531
20120629
20120731
20120831
20120928
20121031
20121130
20121231
20130131
20130228


Gilead Stock Price
Jun 13-May 14
$90
$80
$70
$60
$50
$40
$30
$20
$10
$0
20130628
20130731
20130830
20130930
20131031
20131129
20131231
20140131
20140228
20140331
20140430
20140530



1.9 Lilly's Stock price change based on the drug approval data from Table 1 above




Eli Lilly Stock Price
Apr 07-Mar 08
$60
$58
$56
$54
$52
$50
$48
$46
$44
20070430
20070531
20070629
20070731
20070831
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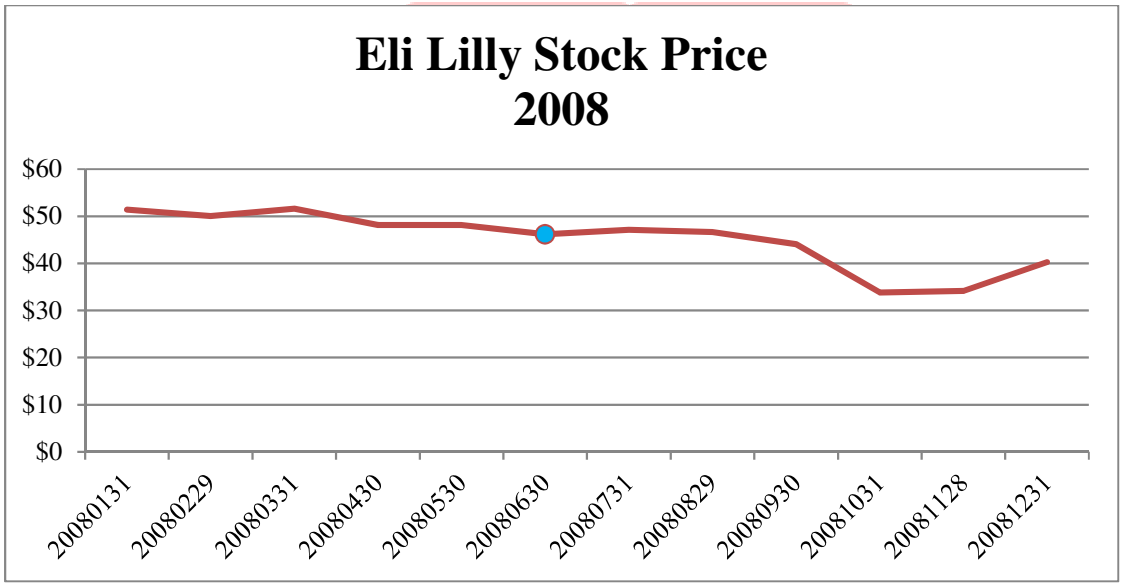
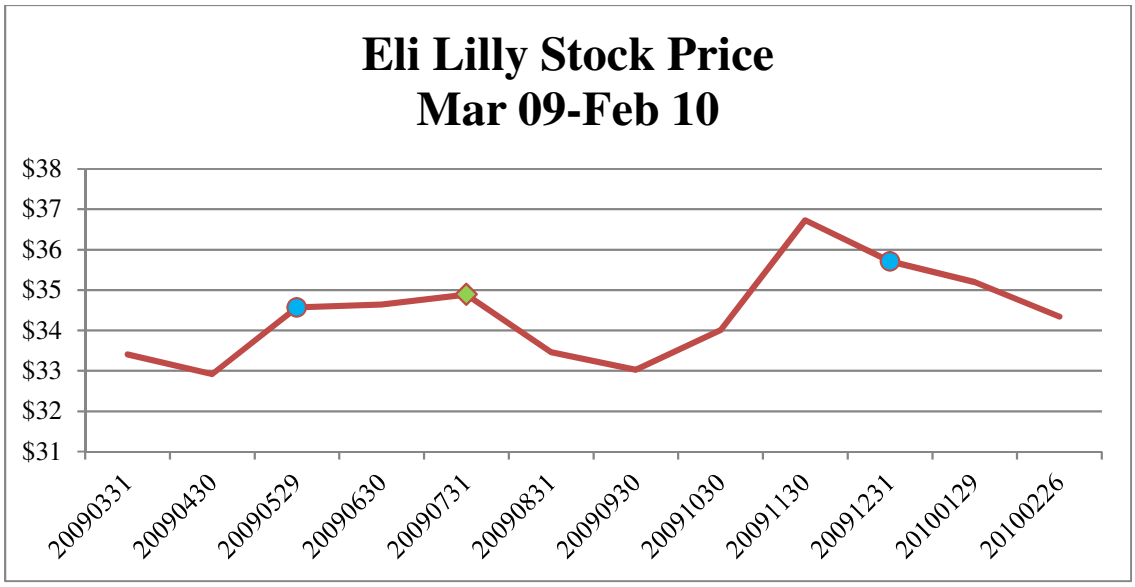
20071031
20071130
20071231
20080131
20080229
20080331


Eli Lilly Stock Price
2008
$60
$50
$40
$30
$20
$10
$0
20080131
20080229
20080331
20080430
20080530
20080630
20080731
20080829
20080930
20081031
20081128
20081231


Eli Lilly Stock Price
Mar 09-Feb 10
$38
$37
$36
$35
$34
$33
$32
$31
20090331
20090430
20090529
20090630
20090731
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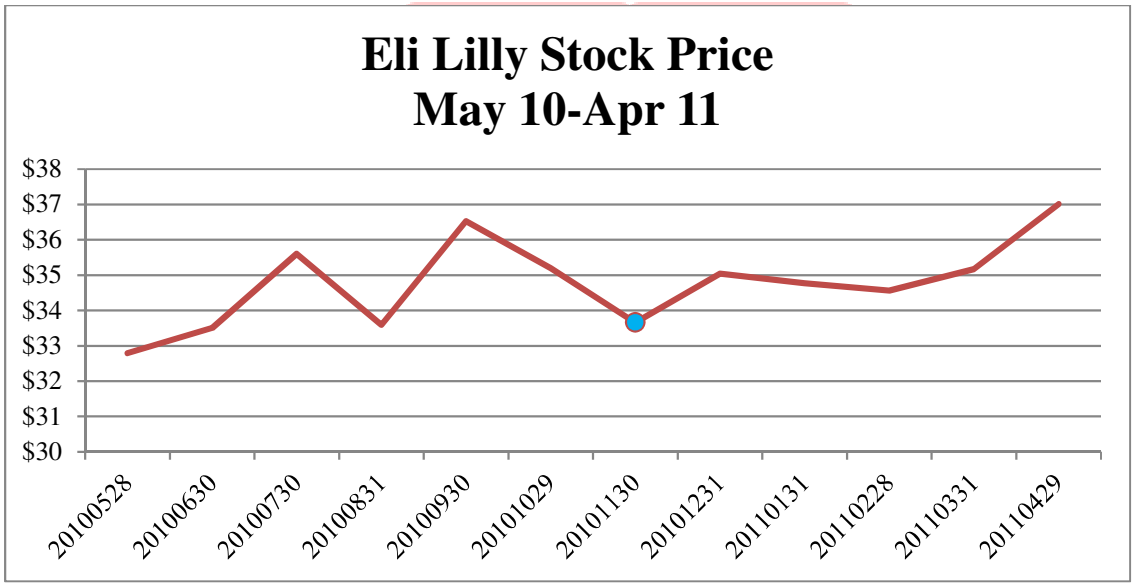
20090930
20091030
20091130
20091231
20100129
20100226


Eli Lilly Stock Price
May 10-Apr 11
$38
$37
$36
$35
$34
$33
$32
$31
$30
20100528
20100630
20100730
20100831
20100930
20101029
20101130
20101231
20110131
20110228
20110331
20110429

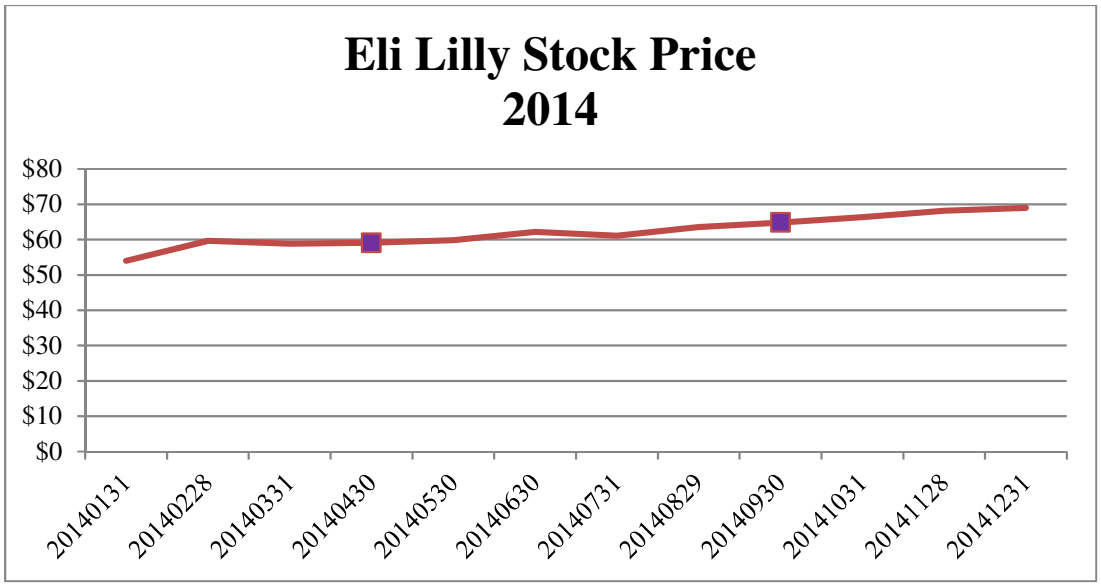


Table 3

	No FDA Review Classification Code (Blockbuster)			
	> 2%	< 2%	< 2%	>2%
Company	**Large Decrease**	**Small Decrease**	**Small Increase**	**Large Increase**
Johnson and Johnson				
Pfizer				
Bristol-Myers Squibb			1	2
Amgen	1	1	2	1
Biogen			1	1
Celgene				
Merck		1		
Gilead				
Lilly			1	1
Totals	**1**	**2**	**5**	**5**

Chart 3.1

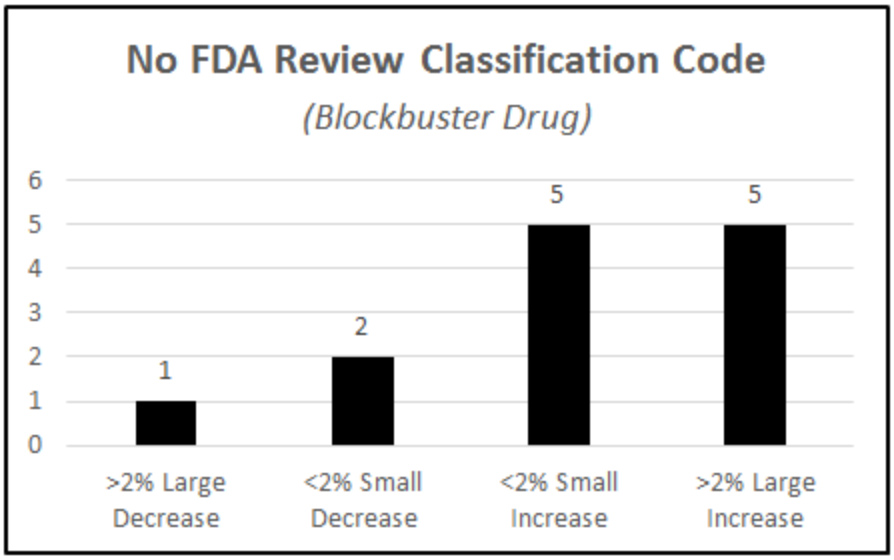


Table 4

	Priority Review			
	> 2%	< 2%	< 2%	> 2%
Company	Large Decrease	Small Decrease	Small Increase	Large Increase
Johnson and Johnson				
Pfizer	1	2	1	
Bristol-Myers Squibb	1	1	2	1
Amgen	1			
Biogen				
Celgene				2
Merck	1	1	1	4
Gilead	3		1	5
Lilly	1		1	1
Totals	**8**	**4**	**6**	**13**

Chart 4.1

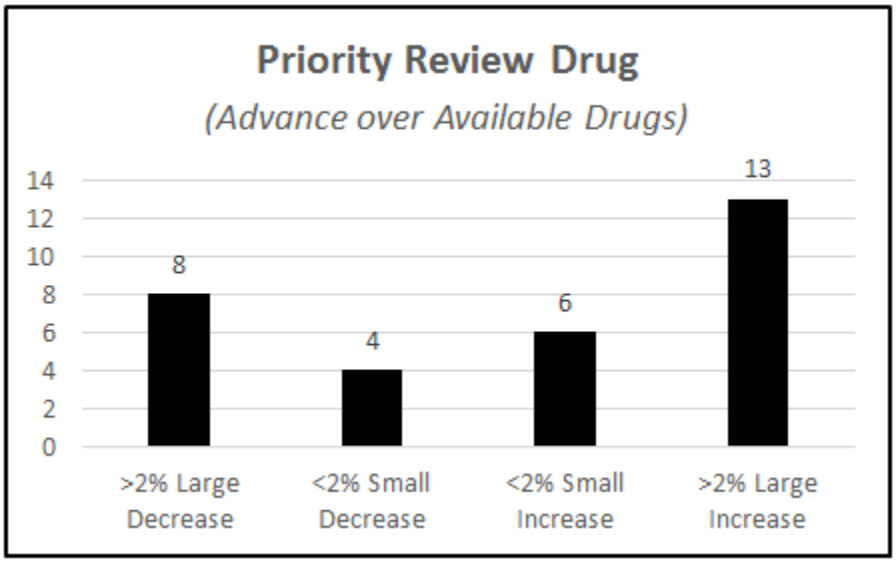
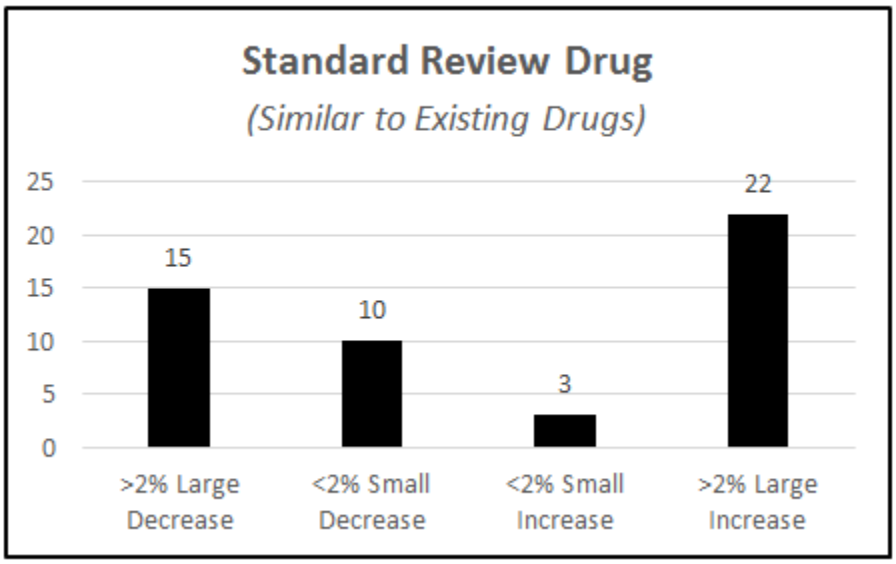


Table 5

	Standard Review Drug			
	> 2%	< 2%	< 2%	> 2%
Company	Large Decrease	Small Decrease	Small Increase	Large Increase
Johnson and Johnson	1			
Pfizer	5	1	1	7
Bristol-Myers Squibb				
Amgen				
Biogen				1
Celgene	1	2		2
Merck	4	3	2	8
Gilead		2		3
Lilly	4	2		1
Totals	**15**	**10**	**3**	**22**

Chart 5.1



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