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Pharma/Device Enforcement: A Year in Review

Introduction

Pharmaceutical and medical device companies faced another year of aggressive and increasingly coordinated enforcement actions from the Department of Justice (DOJ), Food and Drug Administration (FDA), and HHS Office of Inspector General (OIG). Although the number of federal settlements (13) against drug and device makers in 2011 decreased from the prior record-setting year,[1] DOJ secured more than $1.4 billion in penalties and fines from industry participants.

While fewer than half (6) of this year's settlements with pharmaceutical and device companies included a Corporate Integrity Agreement (CIA), most companies either had or now have a CIA in place. The proliferation of CIAs has created a somewhat reliable model for corporate compliance programs; in 2011, however, OIG previewed its intention to reassess the effectiveness of common CIA provisions.

FDA and DOJ obtained 21 criminal convictions across all industries under the Food, Drug and Cosmetic Act (FDCA) in 2011.[2] In doing so, regulators reaffirmed their commitment to holding individual corporate officers accountable for alleged regulatory shortcomings — an enforcement initiative culminating in the sentencing of four former industry executives to prison.

DOJ Settlements

Although most significant developments in pharmaceutical and device company settlements in 2011 occurred at the federal level, state attorneys general continued to pursue settlements in multistate consortia and individually. For instance, in December 2011, Texas Attorney General Greg Abbott secured an $84 million settlement with pharmaceutical manufacturer Actavis Mid-Atlantic in connection with the company's alleged improper reporting of drug prices to the Texas Medicaid program.

1 DOJ secured 21 federal settlements against drug and device makers in calendar year 2010, with recoveries totaling more than $4 billion. The Department has recovered more than $30 billion under the False Claims Act since the law was amended in 1986 and $8.7 billion since January 2009. This Alert presents settlement data associated with calendar year 2011. Settlement amounts from the federal fiscal year (FFY) are not discussed unless specifically noted.

2 Department of Justice, OPA, Press Release, *Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011* (Dec. 19, 2011) (*available at* http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html).

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

John T. Bentivoglio
Washington, D.C.
202.371.7560
john.bentivoglio@skadden.com

Jennifer L. Bragg
Washington, D.C.
202.371.7980
jennifer.bragg@skadden.com

Mitchell S. Ettinger
Washington, D.C.
202.371.7444
mitchell.ettinger@skadden.com

Michael K. Loucks
Boston
617.573.4840
michael.loucks@skadden.com

Gregory M. Luce
Washington, D.C.
202.371.7310
greg.luce@skadden.com

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Four Times Square, New York, NY 10036
Telephone: 212.735.3000
WWW.SKADDEN.COM

DOJ maintained its hard-line enforcement stance towards pharmaceutical and device companies. Across the healthcare industry, in FFY 2011, entities and individuals paid over $2.4 billion to resolve healthcare-related False Claims Act (FCA) allegations.[3] A table describing 2011 pharmaceutical- and device-related DOJ settlements and a list of risk areas for DOJ investigations may be found at Appendix A.

By the Numbers: DOJ Settlements in 2011

Total Settlements: 13
Sector: Pharmaceutical: 9
Sector: Medical Device: 4

Settlements By Company Size
Large: 10
Small: 3

Settlement Amounts (criminal and civil)
> $100 million: 2
> $20 million: 6

Total Recoveries: $1.45 billion (approx.)

Settlements with Criminal Component: 4
Misdemeanor pleas: all 4 of the misdemeanor cases involved off-label promotion

Categories of alleged misconduct:
Off-label promotion: 7
Inducements/Payments: 4
False Warrantees: 1
Medicare Fraud: 1

Several 2011 cases are of particular note, including the Elan, Merck and UCB matters. DOJ's main point of emphasis in the Merck case was the company's alleged misbranding of VIOXX® via the sale of the drug without adequate directions for its intended, but off-label, use. FDA's "intended use" regulations have emerged as DOJ's primary tool for prosecuting alleged off-label promotion. DOJ aggressively pursued civil and criminal charges against Merck, resulting in the most severe sanctions of the year: a misdemeanor guilty plea, $322 million in criminal fines and penalties, and $628 million in civil penalties and damages. The Merck investigation was conducted jointly by OIG, FDA, DOJ and the offices of various state attorneys general. Enforcement agencies took these actions despite the company's early withdrawal of VIOXX® from the market and close coordination with the FDA in responding to product safety concerns.

The Elan Pharmaceuticals case represents prosecutors' continuing focus on incentives employed to encourage off-label prescriptions. DOJ alleged Elan generated call plans that included physicians unlikely to prescribe on-label. The company, prosecutors alleged, tied incentive compensation to total sales — without regard to physician specialty or patient population — in order to drive off-label prescriptions. The company entered a misdemeanor guilty plea to one violation of the FDCA and made a global payment of $203 million to resolve the criminal and civil investigations.

Finally, the UCB case was notable for the government's focus on the company's medical affairs division, alleging that medical science liaisons (MSLs) recruited and paid physicians to participate in retrospective studies regarding an off-label use. Company MSLs also were alleged to have participated in the preparation of marketing posters that represented that an off-label use was safe and effective, despite being aware of a failed pilot study. The case resulted in a misdemeanor plea and $35 million in fines and penalties.

The pace and volume of healthcare enforcement cases shows no sign of abating in 2012. The number of matters initiated by whistleblowers hit an all-time high of 638 in 2011.[4] Several major DOJ

3 *Supra* note 2.

4 *Id.*

investigations may be resolved in 2012. In November 2011, GlaxoSmithKline announced it took a $3 billion reserve to resolve federal and state investigations involving the company's marketing practices for Avandia® and eight other drugs. Similarly, Abbott has taken a $1.5 billion reserve to resolve DOJ allegations around the marketing of Depakote®, Amgen has announced a set-aside of $780 million to resolve various FCA whistleblower complaints related to reimbursement and sales activities, and Ranbaxy earmarked $500 million to resolve a good manufacturing practices (GMP) dispute with DOJ.

FDA Enforcement Trends

FDA had an active 2011, resolving investigations against several drug and device companies by consent decree. This year reaffirmed that the signing of a consent decree often represents the beginning, not the end, of the story. The violation of a consent decree can trigger additional obligations, including substantial monetary fines and penalties. Furthermore, entry of a consent decree does not necessarily preclude later criminal investigation and prosecution. For example, although GlaxoSmithKline entered a consent decree in 2005, the company's subsidiary, SB Pharmco Puerto Rico, nonetheless pled guilty to a felony violation of the FDCA in October 2010 for the same conduct.

FDA continued aggressive use of its seizure and injunctive authorities, with injunctive actions reaching an apparent decade-long high of 20. FDA also increased its utilization of other administrative remedies including, most notably, debarment. In 2009, the agency observed that its use of debarment proceedings was on the rise.[5] The number of debarments in 2011 bears out this growing trend. FDA debarred 19 individuals in 2011. This figure more than doubles the number of debarments in 2010 and nearly matches the prior three years combined.[6] The duration of debarments ranged from three years (1) to five years (6) to permanent (9). A table summarizing 2011 FDA enforcement actions and trends may be found at Appendix B.

In October 2011, FDA released for comment a report containing eight draft proposals as part of the agency's ongoing effort to make publicly available compliance and enforcement information more easily accessible.[7] Once complete, FDA's Transparency Initiative will make available to the public, among other things, (i) FDA evaluations of marketing materials, (ii) expanded disclosure of Untitled Letters, and (iii) information about recall and enforcement activities, including information relating to inspection results.

Finally, in 2011, FDA published revised guidelines for the submission and review of prosecution recommendations, introducing for the first time special procedures and considerations for prosecuting senior-level corporate officers.[8] The guidelines echo FDA's sister agencies' view that knowledge of and actual participation in underlying misconduct are not prerequisites to prosecution.[9]

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5 Government Accountability Office, *Oversight of Clinical Investigators: Action Needed to Improve Timeliness and Enhance Scope of FDA's Debarment and Disqualification Processes for Medical Product Investigators*, No. 09-807 (Sept. 25, 2009), *available at* http://www.gao.gov/new.items/d09807.pdf.

6 *See* http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm.

7 *Available at* http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf.

8 For more on FDA's criminal prosecution guidelines, *see FDA Revamps Criminal Prosecution Guidelines and Expands Health Care Fraud-Related Investigations*, *available at* http://www.skadden.com/Index.cfm?contentID=51&itemID=2350 (February 9, 2011).

9 For more on prosecution of individuals, *see The Government's Shift in Focus to the Two-Legged Defendant*, available at http://www.skadden.com/Index.cfm?contentID=51&itemID=2345 (January 2011).

Individual Enforcement Actions

If 2010 was punctuated by OIG's exclusion of Marc Hermelin, director of KV Pharmaceuticals and onetime CEO and chair of the company, 2011's hallmark was the unprecedented sentencing of four former executives of Synthes/Norian to prison.[10] The government pursued criminal charges against top executives on the basis of the responsible corporate officer (RCO) doctrine, a strict liability offense that permits conviction of corporate officers who had the power to prevent or promptly correct violations of the FDCA by reason of their position but failed to do so.

The Synthes/Norian case, alleging that the company conducted unauthorized clinical trials and distributed an adulterated bone filler, featured an aggressive prosecutorial stance against company executives at every phase of the investigation. At sentencing, DOJ was permitted to present — over defendants' objections — evidence of fraudulent and deceptive intent, despite the fact that defendants' pleas were to strict liability misdemeanor violations of the FDCA. Prosecutors used evidence of alleged wrongful intent to distinguish the conduct at issue from other RCO cases, thereby justifying the imposition of prison terms at the higher end of federal sentencing guidelines.

OIG's enforcement role centers on its exclusion authority, and with over 3,300 individuals and entities excluded in 2010, OIG has shown no reluctance to impose this grave remedy. Late last year, OIG foreshadowed an even more aggressive use of its exclusion authority, placing a particular emphasis on the exclusion of individuals under 42 U.S.C. § 1320a-7(b)(15), a provision that allows the agency to exclude individuals who control or are managing employees of a sanctioned entity.[11] Noticeably absent from OIG's exclusion list, however, is Forest Laboratories CEO Howard Solomon. In early 2011, following Forest's 2010 $313 million settlement with DOJ, Solomon received notification from OIG that he was being considering for exclusion.[12] OIG determined ultimately not to pursue Solomon's exclusion, informing Solomon that OIG had reviewed the matter and decided not to pursue exclusion.

While the matter was resolved in Solomon's — and Forest's — favor, it demonstrates OIG's emerging emphasis on holding individuals accountable.[13] We believe OIG will routinely review the conduct of senior executives following criminal resolutions with their companies and will refuse to provide up-front assurance about the fate of such executives at the time of resolution with the company.

Compliance Program Developments

For pharmaceutical and device companies entering into CIAs in 2011, the year marked a deepening of trends towards increased transparency and accountability of board members and executives. OIG has come to expect greater transparency, with companies now routinely obligated to provide information on physician speakers, grants, charitable donations and clinical trials. Broad CIA-imposed certifications are becoming a greater risk area for companies generally and chief compliance officers specifically. Boards must certify that the company has implemented an effective compliance program per most CIAs' requirements, and the OIG is likely to more closely scrutinize board oversight activities in the future. Compliance officers must monitor and certify the day-to-day compliance activities of the company. And the scope of individuals required to certify compliance — not only with CIA

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10 http://www.justice.gov/usao/pae/News/2011/Nov/synthesexecs_release.pdf.

11 Mary Riordan, OIG Senior Counsel, *Office of Inspector General Update* (*available at* http://www.ehcca.com/presentations/pharmacongress12/riordan_1.pdf).

12 *See* http://www.frx.com/news/PressRelease.aspx?ID=1550242.

13 Anna Edney, *Drug-Firm Executives Under New Scrutiny in Medicare Fraud*, Washington Post (Nov. 9, 2010), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2010/11/08/AR2010110805757.html.

terms but also federal health care program and FDA requirements generally — is expanding beyond traditional and, arguably, reasonable bounds.

For example, the Annual Report certification by the Chief Compliance Officer in the UCB CIA includes the following: "In addition, UCB's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside UCB have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by UCB and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements." UCB CIA, §V.C.2.d. Arguably, this requires the CCO to certify that the relevant materials "are in compliance with all applicable Federal health care program and FDA requirements." This is problematic on a number of levels. First, the compliance function in most manufacturers does not drive or own the promotional review and approval process. Second, while companies frequently make well-considered judgments about what claims can be included in promotional materials, the FDA frequently disagrees, resulting in the issuance of warning or untitled letters that allege the claims render the product to be misbranded in violation of the FDCA. While it may be fair to require CCOs to certify that certain *processes* have been put in place, and periodically audited and monitored for compliance, it is not fair to require certifications as to the *outcome* of such processes, particularly where the process is not owned by the compliance function and the output of such processes require judgment calls on matters about which people in good faith may disagree.

Monitoring requirements continued to increase in 2011. CIA obligations extended into business areas such as medical affairs, publications, and research and development, though the requirements varied somewhat depending on existing controls. Merck's CIA obligations, for example, exclude any publications controls requirements due to the company's pre-existing voluntarily adopted Publications Protocol Transparency Initiative. The company's CIA, however, mandates the establishment of 21 different policies and guidelines and matches high-water marks set by past CIAs in many respects. A table of monitoring requirements in selected 2011 CIAs may be found at Appendix C.

OIG appears poised to revisit commonly imposed CIA compliance and monitoring requirements. Informally announced late last year, OIG intends to convene in 2012 a one-day roundtable with drug and device company representatives to discuss compliance measures that industry has found to be effective.[14] The dialogue represents a rare opportunity for industry stakeholders — large and small, under a CIA or not — to proactively discuss corporate compliance policies and protocols. The results of the roundtable discussion are not expected to alter the terms of existing CIAs, they will however likely shed light on OIG's view of industry best practices.

Looking Forward to 2012

Though the trend towards more aggressive healthcare enforcement is expected to continue into 2012, legal challenges to novel and established governmental theories of prosecution are making their way into the courts, offering a glimmer of hope. The Second Circuit is primed to rule in *U.S. v. Caronia* on the constitutionality of FDA's regulation of off-label speech.[15] Eleven major drug and device manufacturers submitted an *amicus* brief, joining Caronia's free-speech challenge. Par

14 Riordan, *Office of Inspector General Update.*

15 No. 09-506-CR (2d Cir, 2010).

Pharmaceuticals filed in federal court a declaratory judgment complaint seeking to elicit from FDA clear and defined parameters for truthful, but off-label, promotional speech.[16] These cases demonstrate an increasing industry willingness to challenge vague governmental standards for potentially criminal conduct.

Compliance areas under governmental scrutiny will continue to evolve in 2012 as whistleblowers drive investigators into uncharted territory. While sales and marketing activities are the traditional focus of health care investigations, prosecutors will likely expand to medical affairs, reimbursement support, research and development, and manufacturing. Social media interactions, interactions with compendia, and interactions with physician and patient groups are areas also likely to receive increased attention from regulators. Heightened focus on individuals is expected.

The challenging enforcement environment confronting drug and device companies in 2012 calls for a renewed emphasis on compliance programs and novel approaches to managing government investigations. Such programs should place particular weight on the drivers of corporate behavior, including incentive compensation, personnel evaluations, call plans and sales training programs. Each of these areas can have a powerful impact on how company personnel act, and each should be reviewed to determine whether it is consistent with the company's ethics and compliance goals.

16 No. 11-CV-1820-RWR (D.D.C. 2011).

Appendix A

2011 DOJ Pharma/Device Settlements Table

Company	Allegations	Criminial Component	Total Recovery
DFine Inc.	Inducements	None	$2,400,000
Elan	Off-label promotion	Misdemeanor FDCA	$203,000,000
EMD Serono	Inducements	None	$44,300,000
KV Pharmaceuticals	Off-label promotion	None	$17,000,000
GE Healthcare	Medicare Fraud	None	$30,000,000
Guidant	False Warantees	None	$9,250,000
Medtronic	Inducements	None	$23,500,000
Merck	Off-label promotion	Misdemeanor FDCA	$950,000,000
Novo Nordsk	Off-label promotion	None	$25,000,000
Pfizer	Off-label promotion	None	$14,500,000
Scios	Off-label promotion	Misdemeanor FDCA	$85,000,000
St. Jude	Inducements	None	$16,000,000
UCB	Off-label promotion	Misdemeanor FDCA	$35,000,000
		Total	**$1,454,950,000**

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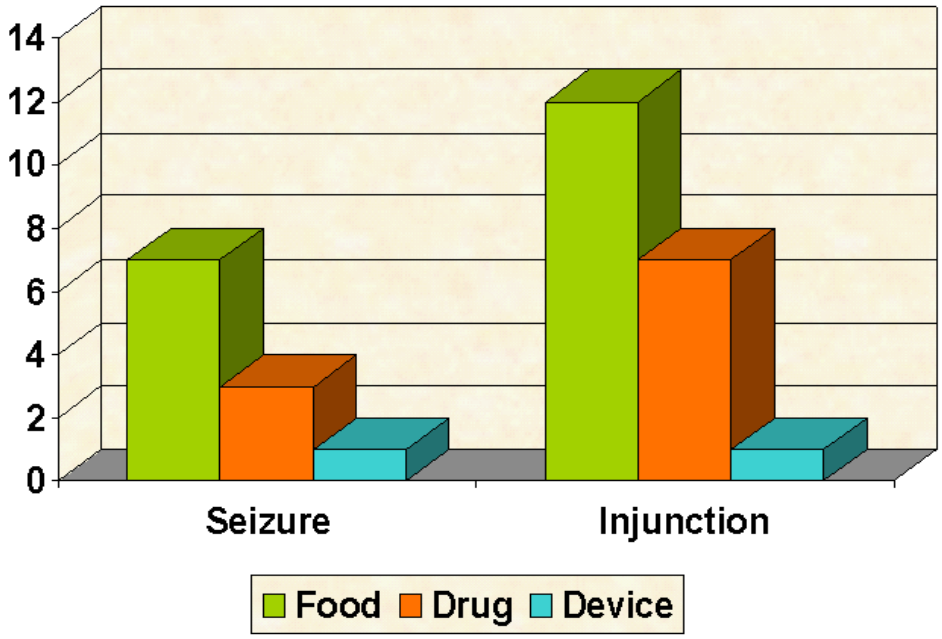
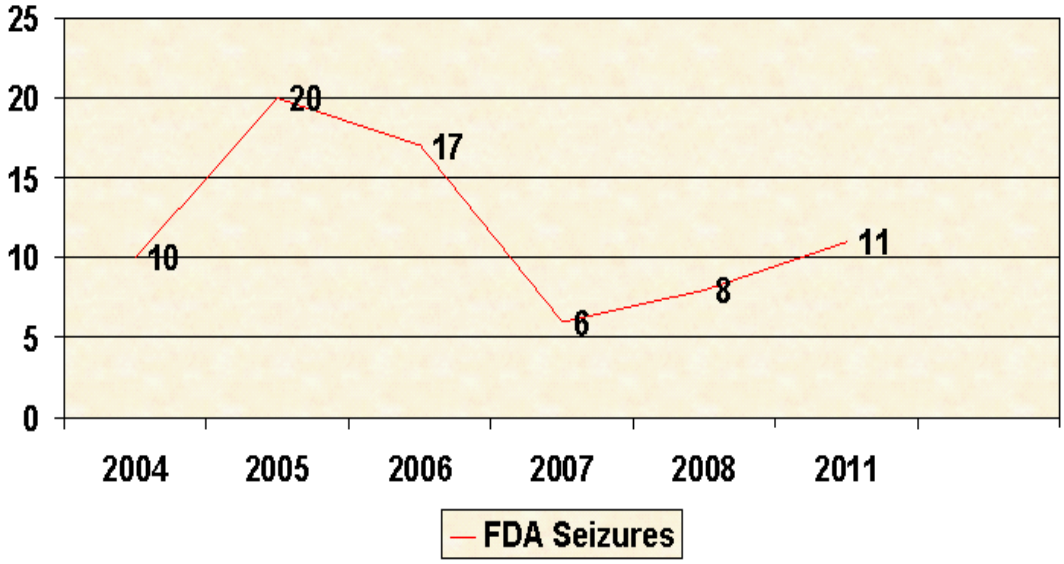
Appendix B

2011 FDA Enforcement Actions



FDA Enforcement Trends[17]

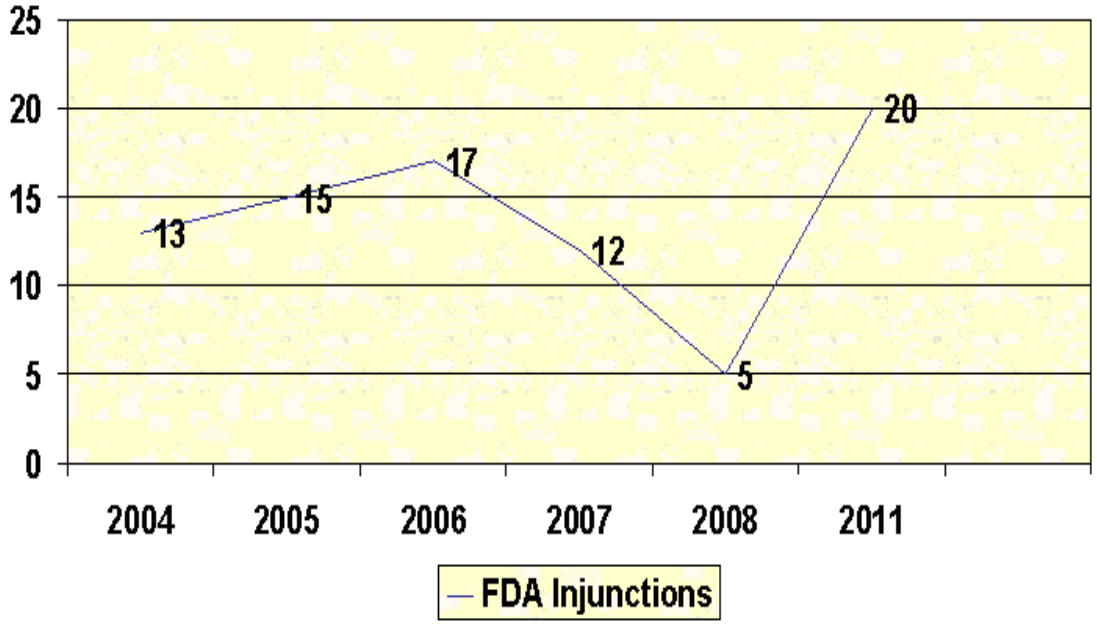


(continued on page 9)

17 Data for FYs 2004 – 2008 available at: http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129823.pdf.

FDA Enforcement Trends

(continued from page 8)



Appendix C

Monitoring Provisions in Selected 2011 CIAs

	Merck	Novo Nordisk	UCB
Ride-Alongs	50	20	20
Speaker Programs	150	50	30
Consultants	50	30	30[18]
Publications	N/A[19]	N/A	5
Grants	30	30	30
Research-Related Activities	30[20]	N/A	8[21]

18 Of the consultant program audits, at least five must be advisory board programs and 25 must be professional services agreements with HCPs.

19 Prior to entering the CIA, Merck voluntarily adopted a Publications Protocol Transparency Initiative, under which Merck voluntarily provides the protocol and statistical analysis plan with any manuscript that Merck submits to a biomedical journal involving Merck-sponsored clinical trials.

20 Of these, 15 must be researcher arrangements and 15 must be investigator arrangements with HCPs or HCIs.

21 Of these, two must related to post-marketing studies.