UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
v.	)	**CRIMINAL NO. 1:10-cr-10431-MBB**
ELAN PHARMACEUTICALS, INC. ,	)	
Defendant.	)	

UNITED STATES' SENTENCING MEMORANDUM

The United States of America submits this memorandum in support of the proposed sentence set forth in the plea agreement entered into by the parties pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C). The defendant, Elan Pharmaceuticals, Inc., is charged with one count of introducing into interstate commerce a misbranded drug, Zonegran, by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352(f)(1). For the reasons set forth below, the government submits that the Court should sentence Elan Pharmaceuticals, Inc., in accordance with the terms of the Plea Agreement. The Court has set the date of February 1, 2011 for the defendant to enter its plea of guilty and to be sentenced.

I. THE PROPOSED GLOBAL RESOLUTION

The proposed global resolution in this case represents the culmination of a complex joint investigation regarding the sales and marketing practices within the United States relating to the Anti-Epileptic drug, Zonegran (also known by the chemical name Zonisamide), by Elan Corporation, plc (hereafter "Elan") and its subsidiary, Elan Pharmaceuticals, Inc. (hereafter "EPI"). The components of the global resolution are as follows:

1. EPI has agreed to plead guilty to one count of introducing into interstate commerce a misbranded drug, Zonegran, by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(1) and 352(f)(1), and to pay a criminal fine in the amount of ninety-seven million fifty thousand two hundred sixty-six dollars ($97,050,266) to be paid within one week of the date of sentencing (*See* Plea Agreement);

2. EPI will pay a mandatory special assessment of $125 pursuant to 18 U.S.C. § 3013, which shall be paid to the Clerk of Court on or before the date of sentencing (*See* Plea Agreement); and

3. EPI will criminally forfeit substitute assets in the amount of $3,600,000 (*See* Plea Agreement);

4. Elan has agreed to settle its federal False Claims Act liability for a total amount of $102,890,517, plus interest (Civil Settlement Agreement, Exhibit B to the Plea Agreement);

5. The United States has agreed not to prosecute Elan for conduct described in a side letter agreement between the United States and Elan (Exhibit D to the Plea Agreement and Corporate Side Letter, attached as Exhibit 1 hereto); and

6. Elan and EPI have agreed to comply with the terms of a Corporate Integrity Agreement (attached hereto as Exhibit 2).

All aspects of the Plea Agreement, including the civil and administrative remedies, are contingent upon the Court's acceptance of the sentence as proposed by the parties .

II. APPLICABLE LEGAL FRAMEWORK

At all times material to allegations set forth in the Information:

The Food and Drug Administration ("FDA") was the federal agency of the United States responsible for protecting the health and safety of the public by enforcing the Federal Food Drug and Cosmetic Act ("FDCA"), 21 United States Code, Section 301, *et seq.* and ensuring, among other things, that drugs intended for use in humans were safe and effective for each of their intended uses and that the labeling of such drugs bore true, complete and accurate information.

The FDCA, and its implementing regulations, required that, with certain exceptions not relevant here, before a new drug could legally be introduced into interstate commerce, a sponsor of a new drug submit and obtain approval of an new drug application ("NDA") from the FDA.

The FDA required that the NDA include proposed labeling for the proposed intended uses of the drug which included, among other things, the conditions for therapeutic use. The NDA was also required to contain, to the satisfaction of the FDA, data generated in adequate and well-controlled trials that demonstrated that the drug would be safe and effective when used in accordance with the proposed labeling.

An NDA sponsor was not permitted to promote and market a new drug until it had an approved NDA, including approval for the proposed labeling. Moreover, if approved, the sponsor was permitted to promote and market the drug only for the medical conditions, uses and dosages specified in the approved labeling. Uses not approved by the FDA, including dosages not approved in the drug's labeling, were known as "unapproved" or "off-label" uses.

The FDCA, and its implementing regulations, required the sponsor to file a Supplemental NDA (or "sNDA"), in order to label or promote a drug for uses or dosages different from the conditions for uses and dosages specified in the approved labeling. The sNDA was required to include a description of the newly proposed indications for use, and evidence consisting of well-controlled clinical studies, sufficient to demonstrate that the drug was safe and effective for the newly proposed therapeutic use. Only upon FDA approval of the sNDA could the sponsor promote the drug for the new intended use.

The FDCA provided that a drug was misbranded if, among other things, its labeling did not contain adequate directions for use. 21 U.S.C. § 352(f)(1). As the phrase was used in the

FDCA and its regulations, adequate directions for use could not be written for medical indications or uses for which the drug had not been approved and proven to be safe and effective through adequate and well-controlled clinical studies.

The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of, or introducing or delivering for introduction into interstate commerce of, any drug that was misbranded. 21 U.S.C. § 331(a).

III. BASIS FOR THE SENTENCE

The United States submits that the following provides a substantial basis for the agreed upon sentence included in the plea agreement:

EPI was a Delaware corporation with its principal place of business in South San Francisco, California. EPI was a wholly owned subsidiary of Elan, a publicly traded Irish corporation headquartered in Dublin, Ireland. During the relevant time frame, EPI developed, marketed and sold pharmaceutical products in the United States. From May 2000 through April 2004, EPI marketed, promoted and sold Zonegran, an anti-epileptic drug ("AED"), within the United States, including in the District of Massachusetts. On April 28, 2004, EPI sold Zonegran, the drug's assets, the United States license to market and sell Zonegran, and the Zonegran sales force to another pharmaceutical company for approximately $128.5 million.

The Zonegran Approval Process

In March 1997, EPI acquired the license for Zonegran from a predecessor company which had filed the NDA for Zonegran with the FDA. In January 1999, EPI became the sponsor of the NDA. On March 27, 2000, the FDA approved Zonegran for use as adjunctive therapy (combination therapy) in the treatment of partial seizures in adults over the age of 16 with

epilepsy (the "approved use").

In its approval letter for Zonegran, the FDA expressly did not approve the use of Zonegran in pediatric patients, and noted specifically that EPI had not fulfilled the required studies to gain approval for use in pediatric patients. At the same time, the FDA raised with EPI concerns about the safety of the use of Zonegran in children due to the incidence of potentially severe side effects, including but not limited to oligohidrosis (decreased sweating) and hyperthermia (overheating).

In response, EPI advised FDA that EPI would conduct Phase 4 (post-marketing) studies on the pediatric use of Zonegran. However, in or about July 2003, EPI made a clear-cut "business decision" to discontinue those studies, but did not notify FDA of this decision until mid-August 2003. EPI never submitted data to the FDA to demonstrate the safety and efficacy of Zonegran for use in children, and the FDA never approved Zonegran for pediatric use.

On or about April 19, 2000, EPI submitted an sNDA to the FDA seeking approval of two lower dosage strengths of Zonegran, 25 mg and 50mg. EPI's market analysis indicated that an approval of the lower doses would increase the opportunity for Zonegran to be used for several off-label or unapproved uses, particularly use in children and in patients who suffered migraine headaches.

From March 2000 through August 2001, EPI advised the FDA that it would conduct Phase 4 clinical studies on Zonegran concerning the safety and efficacy of Zonegran in monotherapy (use alone) and not in combination therapy. EPI never submitted an sNDA for the use of Zonegran in monotherapy and the FDA never approved such use.

In April 2001, EPI analyzed the return on investment of conducting further clinical trials

to obtain FDA approval for additional uses of Zonegran, and explicitly considered the expense of conducting the necessary clinical trials, the time needed to complete the trials, and the pending expiration of the Zonegran patent in March 2005. Over time, EPI made a series of business decisions not to seek FDA approval for any use of Zonegran beyond the approved use or additional doses beyond the lower doses of 25 and 50 mgs, while at the same time making decisions to market Zonegran for the same unapproved uses.

On August 22, 2003, EPI received FDA approval for these two lower dosages of Zonegran. In August of 2003 and thereafter, EPI marketed the newly approved 25 and 50 mg doses of Zonegran as "flexible dosing options" to increase sales of Zonegran for unapproved uses, including for use in children and in patients who suffered migraine headaches.

The FDA never approved Zonegran for any use other than the approved use, and in particular, never approved the use of Zonegran for children; monotherapy; neuropathic pain; migraines or chronic daily headaches; obesity or weight loss; eating disorders such as binge eating, bulimia nervosa and anorexia; psychiatric disorders including mania and bipolar; and movement disorders such as Parkinson's Disease (collectively, the "unapproved uses"). Nevertheless, as detailed below, EPI marketed Zonegran for each of these unapproved uses.

The Limited Market for Zonegran

From on and after 1999 and continuing at least through the date of launch in May of 2000, EPI closely examined the potential markets for all potential uses of AEDs and the actual sales related to these uses. EPI was well aware that over 50% of the AED prescriptions written were for uses beyond Epilepsy. As a result, both prior to and after launch, EPI employees analyzed the potential for sales for uses of Zonegran that were beyond the use applied for in the

Zonegran NDA.

After receiving approval on April 27, 2000, EPI launched its marketing and sales campaign for Zonegran in the United States. Both prior to and after the launch of Zonegran, EPI marketing employees and data analysts conducted extensive evaluations of the Anti-Epileptic Drug ("AED") market. The AED market was divided into "older" and "newer" AEDs – Zonegran was included in the "newer" AED class of drugs. Zonegran was the last of three new AEDs to be introduced to the market during the year 2000, and the last of seven AEDs on the market at that time. The other AEDs had broader approvals from the FDA than did Zonegran.. Zonegran's placement as the last AED to enter the market during 2000 immediately and adversely impacted sales of Zonegran.

In 2000, EPI's first marketing campaign and sales detail aid for Zonegran was called, "A Track Record of Success." This marketing campaign conformed generally to the approved use of the drug. It focused on the safety and efficacy of the drug and included fair balance regarding any adverse effects. This sales aid accurately represented the drug's half-life parameters, *i.e.*, the amount of time that it took the drug to be absorbed by the body, which is a marker of its effectiveness. Half-life parameters were especially important in the treatment of Epilepsy because a constant therapeutic level of drug in a patient's blood stream was required to prevent seizures. The "Track Record of Success" sales aid did not contain any graphic illustration or diagram highlighting the drug's "mechanism of action," as did subsequent campaigns. This sales aid was required to be reviewed by the FDA as part of the approval process prior to the launch of the drug. When using this sales aid during its first year of sales, Zonegran's market share ranged between 0.22% and 1.0%.

In 2002, EPI came under significant financial pressure as a result of, among other factors, an investigation into EPI's financial practices by the Securities and Exchange Commission, during which EPI's stock prices dropped from a high of $65 per share to $2 per share in six months. As a result, EPI evaluated various means to raise cash, including which drugs to divest and which drugs to retain because of potential profit. As part of that evaluation, EPI conducted market research and decided to retain Zonegran because of its large potential for growth. In these documents, EPI's marketing and sales teams noted that the areas of potential growth were particularly in the areas of unapproved uses. With these areas of growth in mind, EPI developed marketing and sales strategies to capture these off-label markets.

Sales Campaigns Designed to Obtain Off-Label Sales

In response to its financial difficulties, EPI developed a series of promotional sales campaigns to obtain additional revenues through sales of Zonegran for unapproved uses. These sales and marketing campaigns became increasingly and deftly directed to off-label uses.

A. ***Expect More***. In or about April 2002, EPI launched a promotional campaign for Zonegran entitled, "***Expect More, Expect Zonegran***," that included the direction to the sales force to:

* "**Expect More than adjunctive therapy for partial seizures**. *Sell MOAs [mechanisms of action]– allows physician to think beyond just partial seizures."*
* "**Expect more than just use in epilepsy.** *Opens doors for psychiatry, pain, headache, etc."*

The sales aid for the campaign included a diagram that highlighted Zonegran's "Multiple Mechanisms of Action" which related primarily to unapproved uses for Zonegran in psychiatric

disorders, movement disorders, obesity or weight loss, pain management and headaches. The sales force was trained to use these sales aids to generate off-label sales of Zonegran.

B. ***Demand More***. In or about December 2002, EPI introduced the **"Demand More**" promotional campaign which included a sales aid that depicted a group of young adults holding hands, climbing a mountain, and a graphic diagram that highlighted Zonegran's "multiple and complementary mechanisms of action." This sales aid included, among other claims, misleading information such as (I) a comparison chart of the potential mechanisms of action of Zonegran with that of its competitor drugs, noting that only Zonegran covered each of the highlighted characteristics, a chart which was not based upon any head-to-head clinical trials; and (ii) the misleading claim that "Zonegran has the longest half-life of the newer AEDs," a claim not based on any head-to-head clinical trials, and which was true only when Zonegran was used alone, or as monotherapy, an unapproved use.

C. ***Drug T Comparison Flashcard***. In early 2003, EPI created a "***Zonegran-Drug T Comparison Flashcard***" to go "head-to-head" with Drug T, which had a broader indication and was well-known to be used for chronic and migraine headaches for which it eventually received approval through an sNDA. The training guide for the sales force explained that: "[t]his hard hitting tool is going to help you take share from Drug T and this primer is going to show you how!" The flashcard contained misleading information regarding the number of patients who had been treated by each drug; misleading claims relating to the similarity in efficacy of the drugs, unsupported claims regarding Zonegran's multiple mechanisms of action, improper claims of differentiation between the drugs and unsupported claims of the superiority of Zonegran. The sales force was told by EPI "never" to leave the flashcard behind, and to "use it

until they [the FDA] pull it."

D. ***Go Beyond the Max***. Early in 2003, EPI targeted Drug T as Zonegran's number one competitor and used a double entendre to get the implied message of superiority across to the physicians. This sales aid also featured people engaging in physical activities that members of the sales force believed were uncommon for patients who suffered from epilepsy, such as snowboarding. The sales aid contained an even more detailed graphic diagram that emphasized the "Multiple Mechanisms of Action" and highlighted qualities of Zonegran that were unrelated to use in epilepsy. The training materials for the sales force indicated, among other messages, that: "ZONEGRAN has also been shown to increase the levels of serotonin in the hippocampus" and that "[r]esearch has shown that the serotonergic and dopaminergic effects of ZONEGRAN are important to physicians who use AEDs for other purposes beyond epilepsy."

EPI's Promotional Techniques to Sell Zonegran for Unapproved Uses

Throughout the time that it sold Zonegran, EPI deliberately promoted Zonegran for uses other than the approved use, including with false and/or misleading claims of safety and efficacy, through the following methods, among others:

From the launch of Zonegran and thereafter, EPI identified physicians who were top priorities for sales calls on "target lists" for the Zonegran sales force. The "target lists" included not only neurologists who treated adults with epilepsy, but also physicians who did not treat epilepsy at all. At various relevant times, those "target lists" included neurologists who specialized in pediatrics; pain specialists; anesthesiologists; physical rehabilitation specialists; neurologists who specialized in migraines and chronic daily headaches; and child and adult psychiatrists.

EPI trained, directed, and encouraged the sales representatives to promote Zonegran for unapproved uses, including among others, pediatric use, pain, psychiatric disorders, chronic headaches/migraines, and movement disorders. EPI set sales quotas for the Zonegran sales representatives which took into account all sales. Sales representatives were unable to reach these goals unless they actively promoted Zonegran for unapproved uses. When sales representatives complained to their district managers that they were unable to reach their goals selling for the approved use, they were directed to sell the drug for unapproved uses. Sales bonuses were calculated on the numbers of prescriptions written by doctors for any use of the drug, not just for the approved use. Thus, sales representatives actively promoted Zonegran for the unapproved uses to obtain sales and to reach their sales goals under the direction of company management.

EPI developed and designed sales aids to assist the sales representatives in promoting Zonegran for unapproved uses through discussions with non-epilepsy doctors. The sales aids were accompanied by training materials called "primers." The primers contained examples of specific dialog to be used by the sales representatives to explain the off-label meaning of graphic illustrations and diagrams to doctors. The graphic illustrations and diagrams were designed to depict chemical reactions related to non-epilepsy conditions. Through use of the diagrams and sample scripts in the primers, sales representatives led doctors into conversations concerning unapproved uses for Zonegran. Sales representatives routinely used these guides to promote Zonegran for uses other than the approved use of the drug.

EPI used sham physician requests for medical information about unapproved uses in order to provide unsolicited information to physicians about unapproved uses for Zonegran in

the form of "Medical Letters." The sales representatives were encouraged to use, and did use, these medical letters to detail physicians. One particular medical letter used by sales representatives with pediatricians described how to administer Zonegran to a child by putting contents of a Zonegran capsule into applesauce. No mention was made about the fact that the FDA had specifically not approved Zonegran for use in children due to the severe potential side effects of oligohidrosis and hyperthermia.

EPI routinely provided promotional samples of Zonegran to physicians who EPI knew did not treat epilepsy. In August of 2002, when the company was expanding target lists to include psychiatrists, they began this sales promotion by delivering Zonegran samples to psychiatrists.

EPI funded purportedly independent continuing medical education programs ("CME") with the purpose of disseminating messages to promote Zonegran for unapproved uses, including specifically for chronic headache, bipolar and acute mania, for children, for obesity and pain. EPI hired advertising agencies to prepare standard promotional slides for Zonegran, had the slides certified by other vendors as "CME," and distributed the slides to advocates for use in presentations.

EPI employed a "robust publication strategy" whereby EPI initiated, funded, sponsored articles to be written about how to prescribe Zonegran for unapproved uses. In some instances, EPI drafted or caused articles and presentations to physicians to be ghostwritten by EPI employees or third-party vendors about the benefits of Zonegran for unapproved uses. EPI trained the sales force to detail physicians using these publications on unapproved uses.

EPI conducted “so-called” Advisory Board Meetings for physicians in exotic vacation

spots such as Bermuda; Key Largo, Florida; Vail, Colorado; Banff, Canada and Tucson, Arizona. During these conferences potential high prescribing physicians were invited on all expense-paid trips to hear speeches on the use of Zonegran in pediatric patients, psychiatric disorders including acute mania and bipolar disorder, neuropathic pain, weight loss, pain and chronic headaches. As a result of the sales campaigns and promotional techniques to obtain sales of Zonegran for unapproved uses, the sales of Zonegran increased dramatically. From August 2001 to August 2002, Zonegran prescriptions increased 80.4%; from the 4th quarter 2002 to 4th quarter 2003 Zonegran prescriptions increased 74.1%. Zonegran revenue for the year 2003 was up 87% over 2002 revenue.

In April of 2004, EPI sold Zonegran, the drug's assets, the United States license to market and sell Zonegran, and the Zonegran sales force to another pharmaceutical company for approximately $128.5 million. Although that company took measures to restrict the illegal promotion of Zonegran for unapproved uses, doctors who were previously called upon by the EPI sales force continued to use the drug for unapproved uses based upon the prior conduct of EPI employees. Thus, the effect of the off-label marketing campaign continued well after the drug was sold by EPI.

After the sale of Zonegran, EPI also divested several other drugs sold and marketed by EPI in the United States. Today, the only drug marketed by EPI in the United States is Tysabri, which is co-marketed with another pharmaceutical company. The company's present focus is on research and development in the areas of Alzheimer's Disease, Parkinson's Disease, Multiple Sclerosis and Crohn's disease. For these reasons, the Corporate Integrity Agreement ("CIA") (Exhibit 2) is forward-looking and will cover the marketing and sales of any drugs that may

come to market during the period covered by the CIA.

For all these reasons, the United States believes that the global resolution reached in this case takes into consideration the nature and seriousness of the offense, as well as the need for the sentence imposed. It will promote respect for the law in this highly regulated industry and is just punishment for the offense committed. The fine imposed and the CIA will adequately deter any future criminal conduct by this company. Should another violation occur, the company will be subject to a potential felony charge. 21 U.S.C. § 333(a)(2).

IV. SENTENCING GUIDELINES ANALYSIS AND PLEA AGREEMENT

A. DETERMINATION OF THE CRIMINAL FINE

The parties agreed that the maximum fine for violation of 21 U.S.C. §§ 331(a), 333(a)(1), 352(f)) is a fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571(c)(5) and (d). EPI's pecuniary gain from the misbranded drug, Zonegran, totaled approximately $80,875,222 the maximum possible fine in connection with this charge is $161,750,444.

The parties agreed that while the fine provisions of the United States Sentencing Guidelines do not apply to organizational defendants for misdemeanor violations of the Food, Drug, and Cosmetic Act, *see* U.S.S.G. § 8C2.1, the agreed-upon fine is consonant with those guidelines and takes into account the sentencing factors set forth in both 18 U.S.C. § 3553 (imposition of a sentence) and 18 U.S.C.§ 3572 (imposition of a fine).

The parties agreed that the base fine is $80,875,222, which was the pecuniary gain to EPI from the offense. *See* U.S.S.G. §§ 8C2.4(a), 8C2.3.

The parties also agreed that pursuant to U.S.S.G. § 8C2.5, the culpability score is six (6).

The government determined this score as follows: (a) base culpability score is five (5) pursuant to U.S.S.G. § 8C2.5(a); (b) add three (3) points pursuant to U.S.S.G. § 8C2.5(b)(3) in that the organization had 200 or more employees and tolerance of the offense by substantial authority personnel was pervasive throughout the organization; and (c) deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) in recognition of EPI's full cooperation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

The parties agreed that pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of six (6) is 1.20 to 2.40. Thus, the Guideline Fine Range is $97,050,266 to $161,750,444. *See* U.S.S.G. §§ 8C2.7(a), (b); 18 U.S.C. §§ 3571(c), (d).

The parties agreed that EPI should pay a criminal fine of $97,050,266 for the violation in Count One of the Information. This fine amount is within the Guideline Fine Range and is appropriate as this amount takes into consideration the relevant sentencing factors discussed above.

B. PROBATION

The government did not seek a period of probation because of the comprehensive and forward-looking five-year CIA that was executed between Elan and the Office of the Inspector General of the Department of Health and Human Services ("OIG"). *See* Exhibit 2 attached. As previously noted, EPI is a wholly owned subsidiary of Elan. The five-year CIA requires Elan to implement a compliance program that addresses present and future promotional activities and regulatory functions. Among other things, the CIA requires that the Board of Directors (or a committee of the Board) annually review the company's compliance program with the help of an outside expert and certify its effectiveness; that certain senior executives annually certify that

their departments or functional areas are compliant; that Elan send doctors a letter notifying them about the settlement; and that the company post on its website information about payments to doctors, such as honoraria, travel or lodging. Elan is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches. The OIG has entered CIAs with hundreds of other providers and has a well-established CIA monitoring process. Accordingly, the government submits that OIG is in the best position to effectively monitor the conduct of the relevant entities, Elan and EPI, going forward.

C. VICTIMS AND RESTITUTION

EPI will plead guilty to one count of introducing into interstate commerce a misbranded drug Zonegran by reason of the drug being inadequately labeled for its intended uses in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(f).

The Victim and Witness Protection Act, 18 U.S.C. § 3663 ("VWPA") and the Mandatory Victim Restitution Act ("MVRA"), 18 U.S.C. § 3663A, are not directly applicable in this case because the offense to which EPI will plead guilty is not covered by these statutes. See 18 U.S.C. § 3663(a) (covering restitution only for offenses under Title 18; 21 U.S.C. §§ 841, 848(a), 849, 856, 861 & 863; and 49 U.S.C. §§ 5124, 46312, 46502 & 46504 except when the MVRA applies); 18 U.S.C. § 3663A(c)(1) (covering restitution only for crimes of violence under 18 U.S.C. § 16; offenses against property under Title 18 or 21 U.S.C. § 856(a); and offenses described in 18 U.S.C. § 1365). Although the Court has the authority to order restitution as a condition of probation, 18 U.S.C. § 3563(b)(2), or supervised release, 18 U.S.C. § 3583(d), and pursuant to U.S.S.G. § 5E1.1(a)(2), as mentioned above, the government does not seek a period

of probation or supervised release in this case because of the existence of a comprehensive CIA between Elan and the Department of Health and Human Services.

The Civil Settlement Agreement resolving the Civil Action (Exhibit B to the Plea Agreement), requires the payment of $102,890,517, plus interest, which resolves the claims for reimbursement for Zonegran by any federal and state health care programs. The parties agreed that the complication and prolongation of the sentencing process that would result from an attempt to fashion any additional restitution order outweighs the need to provide restitution to potential victims in this case, especially where, as here: (1) any loss suffered by government payers will be compensated fully as defined in the Civil Settlement Agreement, and (2) given the numerous unknown individuals and insurance companies that purchased Zonegran more than six years ago, tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the product at issue would be extraordinarily complicated, if not impossible. *See* 18 U.S.C. § 3663(a)(1)(B)(ii). Accordingly, the United States agreed not to seek a separate restitution order as to EPI as part of the resolution of the criminal case.

In addition, under any of the above provisions, even if they were to apply, the Court may decline to make an order of restitution if it determines that the complication and prolongation of the sentencing process outweighs the need for restitution. 18 U.S.C. §§ 3663(a)(1)(B)(ii), 3663A(c)(3)(B). *See also* U.S.S.G. § 5E1.1(b)(2). Determining actual victims from the conduct, and the harm resulting therefrom, is a complicated process. This is especially true when the defendant has divested the subject drug, Zonegran, more than six years ago. Indeed, should a single entity or individual make a claim for restitution in this matter, the Court would likely be

required to hold a mini-trial to determine whether the claimant is a victim at all, and, if so, whether the claimant suffered any losses. The parties contend that determining complex issues of fact related to the cause or amount of any victim's losses would complicate and prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process.

D. FORFEITURE

The forfeiture component of the plea agreement and Information arises from the FDCA's provision for seizing misbranded and unapproved drugs. 21 U.S.C. § 334 (allowing proceedings on libel of information, for condemnation, against drugs that are misbranded, adulterated or unapproved so that the government can seize or destroy them). These proceedings are by their nature classic civil forfeiture proceedings. Under federal forfeiture law, the government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress which contains a civil forfeiture remedy. *See* 28 U.S.C. § 2461(c) (allowing criminal forfeiture where the defendant is charged "in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized ..."). Thus, if civil forfeiture is authorized in a statute such as the FDCA, then criminal forfeiture is as well. As the misbranded drug (Zonegran) is no longer available for seizure or destruction, the government can seek substitute assets as it has done here. *See* 28 U.S.C. § 2461(c) (the procedures set forth in 21 U.S.C. § 853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available).

As noted earlier, EPI sold the license to sell Zonegran in the United States in April of 2004. Therefore, the parties agreed that EPI should forfeit $3,600,000 in substitute assets for

the misbranded Zonegran which cannot be located upon exercise of due diligence, or which have been transferred or sold to, or deposited with a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty.

V. CONCLUSION

The United States therefore respectfully recommends and requests that the Court enter the agreed-upon sentence set forth in the plea agreement and described herein.

Respectfully submitted,

CARMEN M. ORTIZ
UNITED STATES ATTORNEY

DATED: January 18, 2011 By: */s/ Mary Elizabeth Carmody*
MARY ELIZABETH CARMODY
ANTON P. GIEDT
Assistant U.S. Attorneys

/s/ Patrick H. Hearn
PATRICK H. HEARN
Trial Attorney
Office of Consumer Litigation
United States Department of Justice

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Mary Elizabeth Carmody
MARY ELIZABETH CARMODY
Assistant U.S. Attorney

U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
1 Courthouse Way
Suite 9200
Boston, Massachusetts 02210

December 8, 2010

Joshua S. Levy, Esq.
Ropes & Gray LLP
800 Boylston Street
Boston, MA 02199-3600

John C. Dodds, Esq
Morgan Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103

Re: **Side Letter Agreement with Elan Corporation plc**

Dear Mr. Levy:

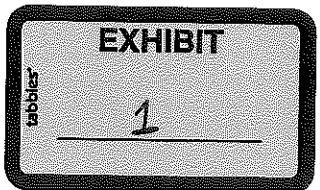
This letter ("Side Letter Agreement") will confirm that, in exchange for full performance of the Plea Agreement entered into by and among the United States of America, acting through the United States Attorney for the District of Massachusetts ("U.S. Attorney") and the Department of Justice (collectively referred to as "the United States") and your client, Elan Pharmaceuticals Inc. ("EPI") a copy of which plea agreement is attached hereto as Exhibit One, and in exchange for certain other promises made herein between and among the United States and your client, Elan Corporation plc (Elan Corporation plc and its subsidiaries collectively will be referred to as "Elan"), the United States and Elan hereby agree as follows:

1. No Criminal Prosecution of Elan Corporation plc

The United States hereby declines prosecution of Elan or any of its subsidiaries (other than EPI as set forth in the Information) for conduct by or attributable to Elan or any of its subsidiaries that:

(a) falls within the scope of the Information to which EPI is pleading guilty; or

(b) was the subject of the Elan investigation by the grand jury relating to the sales, promotion or marketing of Zonegran within the United States, including without limitation, direct or indirect offers or payment of remuneration to third parties within the United States to induce them to recommend, prescribe and/or purchase



Zonegran within the United States; or

(c) was known to the U.S. Attorney or the Office of Consumer Litigation of the Department of Justice prior to the date of this agreement, and which concerned the sales, promotion or marketing of Zonegran within the United States, including, without limitation, direct or indirect offer or payment of remuneration to third parties within the United States to induce them to recommend, prescribe and/or purchase Zonegran within the United States.

The United States does not decline criminal prosecution of Elan or any of Elan's related entities for any other conduct beyond that set forth above.

This Side Letter Agreement is not intended to and does not affect the criminal liability of any individual.

It is understood among the parties to this Side Letter Agreement that the United States' promise not to prosecute Elan is dependent upon and subject to EPI fulfilling its material obligations in the Plea Agreement (Exhibit One) and Elan fulfilling its material obligations herein and in the related Civil Settlement Agreement attached hereto as Exhibit Two. If EPI does not fulfill its material obligations in the Plea Agreement and/or Elan does not fulfill its material obligations herein and in the related Civil Settlement Agreement (Exhibit Two), Elan agrees to waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of the date of this letter, as set forth above, except that Elan retains any such defense that Elan specifically reserved in the parties' tolling agreement dated September 17, 2010, attached hereto as Exhibit Three.

2. Who Is Bound By Agreement

This letter agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys, except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury. This side letter is binding on the Criminal Division of the United States Department of Justice, with the exception of any investigations of Elan Pharmaceuticals, Inc. and/or Elan Corporation plc that are or may be conducted in the future by the Fraud Section of the Criminal Division regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of Zonegran to foreign customers. A copy of the letter to United States Attorney Carmen M. Ortiz on behalf of the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this side letter agreement is attached as Exhibit Four.

It is expressly understood that this Side Letter Agreement will have no effect on state or local prosecuting authorities, except as set forth in the settlement agreements between Elan and the various states.

3. Complete Agreement

This Side Letter Agreement, the Plea Agreement with EPI, the Civil Settlement Agreement, the Corporate Integrity Agreement, the Escrow Agreement between Elan and the United States, and the Tolling Agreement between Elan and the United States Attorney dated September 17, 2010 (incorporating prior tolling agreements), are the complete and only agreements between the parties. No promises, agreements or conditions have been entered into other than those set forth or referred to in the above-identified documents. This agreement supersedes prior understandings, if any, of the parties, whether written or oral. This agreement cannot be modified other than in writing signed by the parties or on the record in court.

If this letter accurately reflects the agreement entered into between the United States and Elan and its Board of Directors has authorized you to enter into this agreement, please sign below and return the original of this letter to Assistant U.S. Attorney Mary Elizabeth Carmody.

Very truly yours,

CARMEN M. ORTIZ
United States Attorney
District of Massachusetts

MARY ELIZABETH CARMODY
ANTON P. GIEDT
Assistant U.S. Attorneys
District of Massachusetts

ACKNOWLEDGMENT OF AGREEMENT

The Board of Directors of Elan Corporation plc has authorized me to execute this Side Letter Agreement and the Civil Settlement Agreement on behalf of Elan Corporation plc. The Board of Directors has been advised of the contents of this Side Letter Agreement, the Civil Settlement Agreement, the Plea Agreement with EPI, the criminal Information charging EPI, and the Corporate Integrity Agreement, and has discussed them fully with its counsel. I am further authorized to acknowledge on behalf of Elan that these documents fully set forth the agreements made between Elan and EPI and the United States, and that no additional promises or representations have been made to Elan and EPI by any officials of the United States in connection with the disposition of this matter, other than those set forth in those documents.

JOHN B. MORIARTY, JR.
Senior Vice President and General Counsel
ELAN CORPORATION PLC

Dated: 12/13/10

JOSHUA S. LEVY, ESQ.
Ropes & Gray
Counsel for Elan Corporation plc

Dated: 12/13/10

JOHN C. DODDS, ESQ
Morgan Lewis & Bockius LLP
Counsel for Elan Corporation plc

Dated:

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JOHN B. MORIARTY, JR.
Senior Vice President and General Counsel
ELAN CORPORATION PLC

Dated:

JOSHUA S. LEVY, ESQ.
Ropes & Gray
Counsel for Elan Corporation plc

Dated: 12/13/10

JOHN C. DODDS, ESQ
Morgan Lewis & Bockius LLP
Counsel for Elan Corporation plc

Dated: 12/13/10

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ELAN CORPORATION, PLC

I. PREAMBLE

Elan Corporation, plc hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). This CIA specifically applies to Elan Corporation, plc and all its corporate subsidiaries, or other Elan affiliates (as defined below) that engage or employ individuals who meet the definition of Covered Persons set forth below in Section II (collectively "Elan"). Contemporaneously with this CIA, Elan Corporation, plc is entering into a Settlement Agreement with the United States. Elan Corporation, plc will also enter into settlement agreements with various States (Medicaid State Settlement Agreements), and Elan Corporation, plc's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, Elan established a compliance program and initiated certain voluntary compliance measures designed to address its U.S. health care operations and compliance with Federal health care program and FDA requirements. Elan shall continue its compliance program through the term of the CIA and shall do so as set forth below. Elan may modify its compliance program as appropriate, but at a minimum Elan shall ensure that during the term of the CIA, it shall comply with the obligations set forth herein.

Elan represents that as of the Effective Date of this CIA (as defined below in Section II.A) with limited exceptions and except as otherwise described to OIG, its employees currently do not engage in Promotion Related Functions (as defined below in Section II.C.6) in the United States. Rather, Elan is primarily a research and development company that currently provides limited support for (not through the use of a field sales force) and distributes one Government Reimbursed Product (as defined below in Section II.C.3). If during the term of this CIA, Elan intends to engage in additional Promotion Related Functions in the United States, Elan shall notify the OIG, in writing, of that intention 120 days prior to commencing such Promotion Related Functions or as soon as

practical subject to any other confidentiality requirements. Elan further agrees that, if Elan intends to engage in additional Promotion Related Functions (either through contractors or employees of Elan) (*i.e.*, field based personnel employed or contracted by Elan to promote Elan Government Reimbursed Products), the OIG will amend and expand the requirements of this CIA to address the additional marketing and promotional operations of Elan in the United States. Elan agrees to provide information to the OIG about the additional intended Promotion Related Functions as necessary for the OIG to appropriately amend the CIA. Elan agrees that it shall not engage in additional Promotion Related Functions in the United States, including by re-instituting or re-establishing a sales force, until after it enters an amended CIA that includes provisions acceptable to the OIG that address such additional promotional activities. The amended CIA would likely be modified, at a minimum, to expand the definition of Covered Persons (Section II.C.1) and Relevant Covered Persons (Section II.C.2), to require additional policies and procedures, training requirements, and monitoring requirements relating to the additional operations of Elan. The amended CIA may also require that the Audit Committee (as defined below in Section III.A.3) retain a Compliance Expert to conduct a review of Elan's Compliance Program.

The provisions of the amended CIA shall be determined at the sole discretion of the OIG after considering, among other things, information and documentation provided by Elan.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Elan under this CIA shall be 5 years from the Effective Date of this CIA, unless otherwise specified. The Effective Date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Elan's final Annual Report; or (2) any additional materials submitted by Elan pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

   a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all officers of Elan Corporation, plc, and all Elan Affiliates (as defined below);

b. all directors of Elan and all Elan Affiliates;

c. all employees of Elan and any Elan Affiliate who are: 1) based in the United States; or 2) based outside the United States and who have responsibilities relating to Government Pricing and Contracting Function, Medical Affairs and Materials Related Functions, or (if applicable in the future) Promotion Related Functions; and

d. all contractors, subcontractors, agents, and other persons who perform Government Pricing and Contracting Functions, Medical Affairs and Materials Related Functions, or (if applicable in the future) Promotion Related Functions on behalf of Elan or any Elan Affiliate.

Notwithstanding the above, the term "Covered Persons" does not include: (i) officers, employees, contractors, subcontractors, agents, of the Elan Drug Technologies line of business; (ii) employees, contractors, subcontractors, agents or other personnel of Elan, or any Elan Affiliate, who perform only manufacturing functions, so long as such personnel do not have responsibilities relating to Government Pricing and Contracting Functions, Medical Affairs and Materials Related Functions, or (if applicable in the future) Promotion Related Functions; and (iii) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Government Pricing and Contracting Functions, Medical Affairs and Materials Related Functions, or (if applicable in the future) Promotion Related Functions as defined below in Sections II.C.4-6, respectively.

3. "Government Reimbursed Products" refers to all Elan pharmaceutical or biological products that are promoted or sold by Elan in the United States and reimbursed by Federal health care programs. This term includes all products promoted or sold by Elan or Elan Affiliates.

4. The term "Government Pricing and Contracting Functions" means the collection, calculation, verification, or reporting of pricing and other information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8, *et seq.*), the Medicare Program (codified at 42 U.S.C. § 1395-1395hhh),

the 340B Drug Pricing Program (codified at 42 U.S.C. § 256(b)), or any other government programs through which health care items or services may be purchased or reimbursed, in whole or in part, by the federal government, and the Veteran's Administration pricing program (the "VA Programs"), as set forth in the Federal Supply Schedule and the Veteran's Healthcare Act of 1992. This definition includes, but is not limited to, the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price (BP), and all pricing and other information reported and used in connection with reimbursement under the health care programs described in this paragraph.

5. The term "Medical Affairs and Materials Related Functions" means the field and headquarters functions associated with (i) providing responses to medical inquiries by health care providers (HCPs); (ii) the functions of Elan's Clinical Science Liaisons (CSLs); (iii) contracting with HCPs in the United States to conduct post-marketing clinical trials and post-marketing studies relating to Government Reimbursed Products; (iv) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; (v) the preparation or external dissemination of promotional or medical information materials about Government Reimbursed Products in the United States by Elan, including those functions relating to any applicable review committees and to Elan's Medical Affairs Department (Medical Affairs); and (vi) the provision of services relating to Government Reimbursed Products.

6. The term "Promotion Related Functions" includes the promotion, detailing, marketing, branding, and/or advertising of Government Reimbursed Products, including but not limited to, through a field sales force.

7. The term "Elan Affiliate" shall mean any entity that is owned or controlled, directly or indirectly, by Elan Corporation, plc, including, but not limited to Elan Pharmaceuticals, Inc., Elan Pharma International Limited, and Elan Drug Delivery, Inc., and whose employees or contractors perform Government Pricing and Contracting Functions, Medical Affairs and Materials Related Functions, or (if applicable in the future) Promotion Related Functions.

8. The term "Third Party Personnel" shall mean personnel who perform Government Pricing and Contracting Functions, Medical Affairs and Materials Related Functions, or Promotion Related Functions who are employees of entities with whom Elan or any Elan Affiliate has or may in the future (during the term of this CIA) enter into collaboration agreements or agreements to co-promote or co-develop a Government Reimbursed Product in the United States. Elan has represented that: 1) Third Party Personnel are employed by entities other than Elan or any Elan Affiliate; 2) neither Elan nor any Elan Affiliate controls the

Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Elan agrees that Elan and Elan Affiliates shall promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7 and V.B.5. Provided that Elan complies with the requirements of Sections III.B.2, V.A.7 and V.B.5, Elan shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Elan shall establish and maintain a Compliance Program that includes the following elements:

A. Chief Compliance Officer and Committee.

1. *Chief Compliance Officer.* Prior to the Effective Date, Elan Corporation, plc appointed an individual to serve as its Chief Compliance Officer. During the term of this CIA, the Chief Compliance Officer shall continue to be authorized to oversee compliance with regard to Elan's U.S. operations, with Federal health care program requirements and FDA requirements, and with the requirements of this CIA. Elan shall maintain a Chief Compliance Officer during the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Chief Compliance Officer shall be a member of senior management of Elan, shall report directly to the Chief Executive Officer of Elan, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of Elan Corporation, plc, and shall be authorized to report on such matters to the Audit Committee at any time. The Chief Compliance Officer shall not be or be subordinate to the Elan Corporation, plc General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Elan as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Chief Compliance Officer shall be limited and must not interfere with the Chief Compliance Officer's ability to perform the duties outlined in this CIA.

Elan shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 5 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Elan established a Compliance Committee and Elan shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as regulatory, government contracting, human resources, audit, operations, legal, medical affairs, and (if applicable) sales and marketing). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Elan shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 5 days after such a change.

3. *Audit Committee Compliance Obligations.* The Audit Committee of the Board of Directors of Elan Corporation, plc, (Audit Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Audit Committee shall, at a minimum, be responsible for the following:

a. The Audit Committee shall meet at least quarterly to review and oversee Elan's Compliance Program, including but not limited to the performance and activities of the Chief Compliance Officer and compliance personnel who are "Covered Persons" under this CIA.

b. For each Reporting Period of the CIA, the Audit Committee shall adopt a resolution, signed by each individual member of the Audit Committee, summarizing its review and oversight of Elan's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Audit Committee of the Board of Directors has made a reasonable inquiry into the operations of Elan's Compliance Program, including the performance of the Chief Compliance Officer and the compliance personnel who are "Covered Persons" under this CIA. Based on its inquiry, the Audit Committee has concluded that, to the best of its knowledge, Elan has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Audit Committee is unable to provide such a conclusion in the resolution, the Audit Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Elan.

Elan shall report to OIG, in writing, any changes in the composition of the Audit Committee of the Board, or any actions or changes that would affect the Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Elan officers or employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Elan business unit is compliant with applicable Federal health care program and FDA requirements, and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Chief Executive Officer of Elan Corporation, plc, the President of Elan Corporation plc, and all appropriate Elan executives, vice-presidents, and directors as would be necessary to ensure that there is a certifying officer or executive-level employee with management responsibility for each of the following functions: Medical Affairs and Materials Related Functions, Government Pricing and Contracting Related Functions, and (if applicable in the future) Promotion Related Functions.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity In the event that I have identified potential issues of noncompliance with these requirements, I have referred all such issues to the Compliance Department for further review and follow-up in accordance with Elan's policies and procedures. Apart from those referred issues, I am not currently aware of any violation of applicable Federal health care program requirements, FDA requirements, and the requirements of the Corporate Integrity Agreement, or the requirements of Elan's policies. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to Effective Date, Elan developed, implemented, and distributed written a Code of Conduct to all Covered Persons. Elan shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

The Code of Conduct shall, at a minimum, set forth:

a. Elan's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in the U.S. in accordance with Federal health care program and FDA requirements;

b. Elan's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Elan's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of Elan's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Elan, suspected violations of any Federal health care program or FDA requirements or of Elan's own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and Elan's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Elan's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Elan shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Elan and/or the appropriate Elan Affiliate shall send a letter to each entity employing Third Party Personnel. The letter shall outline Elan's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Elan's Compliance Program. Elan and/or the Elan Affiliate shall attach a copy of the Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Elan's Code of Conduct and a description of Elan's Compliance Program available to its Third Party Personnel; or (b) represent to Elan and/or the Elan Affiliate that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Within 90 days after the Effective Date, Elan shall implement written Policies and Procedures regarding the operation of Elan's compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. appropriate ways to conduct Government Pricing and Contracting Functions in compliance with all applicable Federal healthcare program and FDA requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

c. appropriate ways to conduct Medical Affairs and Materials Related Functions in compliance with all applicable FDA requirements and Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

d. the materials and information about Government Reimbursed Products that may be distributed by Elan personnel, including Medical Affairs personnel and CSLs, and the mechanisms through, and manner in which, Elan personnel receive and respond to requests for information about Elan's Government Reimbursed Products including the approved and non-FDA approved (or "off-label") uses of the products; the form and content of information disseminated by Elan in response to such requests; and the internal review process for the information disseminated. These Policies and Procedures shall require that Elan personnel refer all requests for information about non-FDA approved ("off-label") uses of Government Reimbursed Products to the appropriate Medical Affairs personnel. These Policies and Procedures shall require that distribution of any reprints of medical journal articles be consistent with applicable FDA requirements;

   The Policies and Procedures shall also require that Medical Affairs develop a database ("Inquiries Database") to track all requests for information about Elan's products to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Elan's Government Reimbursed Products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting HCP or health care institution (HCI) in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Elan (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Elan representative who called on or interacted with the HCP or HCI, if known;

e. the manner and circumstances under which medical personnel from Medical Affairs interact with or participate in meetings or events with HCPs or HCIs and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about Government Reimbursed products, including requests relating to the approved and off-label uses of such products;

f. the funding of grants (including educational or research grants) or charitable contributions. These Policies and Procedures shall be

designed to ensure that Elan's funding complies with all applicable Federal health care program and FDA requirements;

the review of product-related materials and information for or about Government Reimbursed Products by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during the review and approval process and are elevated when appropriate. These Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials about Government Reimbursed Products prior to the distribution or use of such materials in the U.S.; and 2) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up; and

g. disciplinary policies and procedures for violations of Elan's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Elan shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, Elan shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Elan's:

a. CIA requirements; and

b. Elan's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person engaged in Government Contracting and Pricing Functions shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include, at a minimum, a discussion of:

a. all applicable Federal health care program and FDA requirements relating to Government Pricing and Contracting Functions;

b. all Elan Policies and Procedures and other requirements applicable to Government Pricing and Contracting Functions;

c. the personal obligation of each individual involved in Government Pricing and Contracting Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;

d. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

e. examples of proper and improper practices related to Government Pricing and Contracting Functions.

Within 90 days after the Effective Date, each Relevant Covered Person engaged in Medical Affairs and Materials Related Functions shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include, at a minimum, a discussion of:

a. all applicable Federal health care program and FDA requirements relating to Medical Affairs and Materials Related Functions;

b. all Elan Policies and Procedures and other requirements applicable to Medical Affairs and Materials Related Functions;

c. the personal obligation of each individual involved in Medical Affairs and Materials Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;

d. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

e. examples of proper and improper practices related to Medical Affairs and Materials Related Functions.

New Relevant Covered Persons shall receive Specific Training as set forth above within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An Elan employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Government Pricing and Contracting Functions or Medical Affairs and Materials Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area, including applicable Federal health care program and FDA requirements.

5. *Update of Training.* Elan shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or any IRO Review, and any other relevant information.

6. *Computer-based Training.* Elan may provide the training required under this CIA through appropriate computer-based training approaches. If Elan chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Elan shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Elan in assessing and evaluating its Government Pricing and Contracting Functions, its Medical Affairs and Materials Related Functions, and the funding of educational grants and healthcare related charitable contributions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Elan shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Elan, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Elan's systems, processes, policies, procedures, and practices relating to Government Pricing and Contracting Functions, Medical Affairs and Materials Related Functions, and the funding of educational grants and healthcare related charitable contributions (collectively "IRO Reviews").

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess Elan's systems, processes, policies, and procedures relating to the certain aspects of Government Pricing and Contracting Functions and Medical Affairs and Materials Related

Functions (Systems Review). As set forth in Appendix B, if there are no material changes in Elan's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Elan materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods. The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

In addition, each Transactions Review shall also include a review of up to two additional areas or practices of Elan, subject to modification if Elan undertakes additional Promotion Related Functions, related to a Government Reimbursed Products identified by the OIG in its discretion (hereafter "Additional Items".) For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Elan and may consider internal audit work conducted by Elan, Elan's Government Reimbursed Products portfolio, the nature and scope of Elan's activities and arrangements with HCPs and HCIs related to Government Reimbursed Products, and other information known to it. The OIG shall notify Elan of the nature and scope of the IRO Review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Elan shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

c. *Retention of Records*. The IRO and Elan shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Elan) related to the reviews.

2. *IRO Review Reports*. The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in each report is described in Appendix B, which is incorporated by reference.

3. *Validation Review*. In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to

determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Elan shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Elan's final Annual Report shall be initiated no later than one year after Elan's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Elan of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Elan may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Elan agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Elan prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Elan a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the IRO Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Elan currently has a disclosure program that is designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Elan's policies (the "Disclosure Program"). During the term for the CIA, Elan shall maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Elan's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Elan shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual.

The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Elan shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

2. *Screening Requirements.* Elan shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Elan shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Elan shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Elan shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Elan to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Elan understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Elan may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Elan meets the requirements of Section III.F.

3. *Removal Requirement.* If Elan has actual notice that a Covered Person has become an Ineligible Person, Elan shall remove such Covered Person from responsibility for, or involvement with, Elan's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Elan has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Elan shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Elan shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Elan conducted or brought by a U.S.-based

governmental entity or its agents involving an allegation that Elan has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Elan shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to Elan or any Elan Affiliate);

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by Elan.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Elan determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Elan shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reporting of Reportable Events under Sections III.1.a-c.* If Elan determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Elan shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities and/or FDA authorities implicated;

b. a description of Elan's actions taken to correct the Reportable Event; and

c. any further steps Elan plans to take to address the Reportable Event and prevent it from recurring.

4. *Reporting of Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program or FDA authorities implicated.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Elan and the FDA that materially discusses Elan's or a Covered Person's actual or potential unlawful or improper promotion of any products (including any improper dissemination of information about off-label indications) or potential unlawful or improper distribution of Government Reimbursed Products, Elan shall provide a copy of the report, correspondence, or communication to the OIG. Elan shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Elan changes locations or closes a business unit or location engaged in Government Pricing or Contracting Functions or Medical Affairs and Materials Related Functions, Elan shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Elan purchases or establishes a new business unit or location engaged in Government Pricing or Contracting Functions or Medical Affairs Related Services Related Functions, Elan shall notify OIG no later than the earlier of the date the purchase or establishment is publicly disclosed or the operation of the new business unit or location begins. This notification shall include the address of the new business unit or location,

phone number, fax number, Federal health care program provider and/or supplier number, and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

Consistent with the requirements set forth in Section I above, in the event that Elan intends to purchase or establish a new business unit or location engaged in Promotion Related Functions in the United States, Elan shall notify the OIG, in writing, of that intention 120 days prior to commencing such Promotion Related Functions. Elan shall also provide information to the OIG about the intended Promotional Related Functions. Elan agrees that it shall not engage in additional Promotion Related Functions in the United States, until after it enters an amended CIA that includes provisions acceptable to the OIG addressing the Promotion Related Functions.

C. Sale of Unit or Location. In the event that, after the Effective Date, Elan proposes to sell any or all of its business units or locations that are subject to this CIA, Elan shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Elan shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Chief Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. the names of the members of the Audit Committee of the Board of Directors referenced in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of Elan's Code of Conduct required by Section III.B.1;

6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. a) a copy of the letter (including all attachments) required by Section II.C.8 and III.B.2 sent to each party employing Third Party Personnel; b) a list of all such existing co-promotion and other applicable agreements; and c) a description of the entities' response to Elan's letter;

8. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);

9. the following information regarding each type of training required by Section III.C:

a. description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Elan and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to Elan;

12. a description of the Disclosure Program required by Section III.E;

13. a description of the process by which Elan fulfills the requirements of Section III.F regarding Ineligible Persons;

14. a list of all of Elan's locations (including locations and mailing addresses) at which it performs Government Pricing and Contracting or Medical Affairs and Materials Related Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care provider or supplier number(s) (if applicable), and the name and address of each Medicare contractor to which Elan currently submits claims (if applicable);

15. a description of Elan's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

16. the certifications required by Section V.C.

B. Annual Reports. Elan shall submit to OIG annually a report with respect to the status of, and findings regarding, Elan's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee, the Audit Committee, or the group of Certifying Employees described in Sections III.A.2-4;

2. a copy of the resolution by the Audit Committee required by Section III.A.3;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable Federal health care program or FDA requirements);

5. a) a copy of the letter (including all attachments) required by Section II.C.8 and III.B.2 sent to each party employing Third Party Personnel; b) a list of all such existing co-promotion and other applicable agreements; and c) a description of the entities' response to Elan's letter;

6. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

8. Elan's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

9. a summary and description of any and all current and prior engagements and agreements between Elan and the IRO, if different from what was submitted as part of the Implementation Report;

10. a certification from the IRO regarding its professional independence and objectivity with respect to Elan;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or FDA requirements;

12. any changes to the process by which Elan fulfills the requirements of Section III.F regarding Ineligible Persons;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action

relating to all such Reportable Events;

15. a summary describing any communications with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. a description of all changes to the most recently provided list of Elan's locations (including addresses) as required by Section V.A.13; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Elan currently submits claims (if applicable); and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. Certifying Employees: In each Annual Report, Elan shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Chief Compliance Officer: In each Implementation Report and Annual Report, Elan shall include the following individual certification by the Chief Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, Elan is in compliance with all of the requirements of this CIA;

b. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

c. Elan's: 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, any materials

containing claims or information about Government Reimbursed Products intended to be disseminated outside Elan have been reviewed by competent regulatory, medical and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed and elevated when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request.

D. Designation of Information. Elan shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Elan shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Elan:
Fabiana Lacerca-Allen
Senior Vice President and Chief Compliance Officer
800 Gateway Boulevard
South San Francisco, CA 94080

Telephone: 650.616.5006

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Elan may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Elan's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Elan's locations for the purpose of verifying and evaluating: (a) Elan's compliance with the terms of this CIA; and (b) Elan's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Elan to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Elan's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Elan shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Elan's employees may elect to be interviewed with or without a representative of Elan present.

VIII. DOCUMENT AND RECORD RETENTION

Elan shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Elan prior to any release by OIG of information submitted by Elan pursuant to its obligations under this CIA and identified upon submission by Elan as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Elan shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Elan is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt any action that individual States may take against Elan under any applicable settlement agreement between the State and Elan.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Elan and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Elan fails to establish and implement any of the following obligations as described in Section III:

a. a Chief Compliance Officer;

b. a Compliance Committee;

c. the Audit Committee resolution;

d. a written Code of Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons and Relevant Covered Persons;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings;

j. reporting of Reportable Events; and

k. notification of communications with the FDA as specified in Section III.I.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day

after the date the obligation became due) for each day Elan fails to engage an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Elan fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Elan fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of $1,500 for each day Elan fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Elan fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Elan as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Elan fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Elan stating the specific grounds for its determination that Elan has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Elan shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Elan receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Elan may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Elan fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Elan receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Elan has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Elan of: (a) Elan's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Elan shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Elan elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Elan cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Elan has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by Elan to report a Reportable Event and take corrective action as required in Section III.H;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;

d. a failure to engage and use an IRO in accordance with Section III.D; or

e. a failure of the Audit Committee to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Elan constitutes an independent basis for Elan's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Elan has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Elan of: (a) Elan's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Elan shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Elan is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Elan has begun to take action to cure the material breach; (ii) Elan is pursuing such action with due diligence; and (iii) Elan has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Elan fails to satisfy the requirements of Section X.D.3, OIG may exclude Elan from participation in the Federal health care programs. OIG shall notify Elan in writing of its determination to exclude Elan (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Elan's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Elan may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Elan of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Elan shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Elan was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Elan shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Elan to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Elan requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Elan was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Elan had begun to take action to cure the material breach within that period; (ii) Elan has pursued and is pursuing such action with due diligence; and (iii) Elan provided to OIG within that period a reasonable timetable for curing

the material breach and Elan has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Elan, only after a DAB decision in favor of OIG. Elan's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Elan upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Elan may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Elan shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Elan, Elan shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Elan and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Elan;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. The undersigned Elan signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF ELAN CORPORATION

December 14, 2010

JOHN B. MORIARTY, JR.
Senior Vice President and General Counsel
Elan Corporation, plc

DATE

December 14, 2010

FABIANA LACERCA-ALLEN
Chief Compliance Officer
Elan Corporation, plc

DATE

JOHN S. RAH
Morgan Lewis & Bockius
Counsel for Elan Corporation, plc

DATE

JOSHUA S. LEVY
Ropes & Gray, LLP
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12/14/2010
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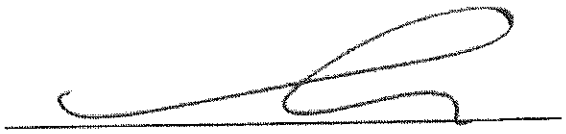
Ropes & Gray, LLP
Counsel for Elan Corporation, plc

12-14-10
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



12/15/10

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

Elan shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Sections V.A.10 and V.A.11 of the CIA, OIG will notify Elan if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Elan may continue to engage the IRO.

If Elan engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Elan shall submit the information identified in Sections V.A.10 and V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, OIG will notify Elan if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Elan may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Government Pricing and Contracting Related Functions, Medical Affairs and Materials Related Functions, and the funding of educational grants and healthcare related charitable contributions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Elan products are reimbursed;

2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Elan.

E. IRO Removal/Termination.

1. *Elan Termination of IRO.* If Elan terminates its IRO during the course of the engagement, Elan must submit a notice explaining its reasons to OIG no later than 30 days after termination. Elan must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Elan to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Elan to engage a new IRO, OIG shall notify Elan of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Elan may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities

and to present additional information regarding these matters. Elan shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Elan prior to requiring Elan to terminate the IRO. However, the final determination as to whether or not to require Elan to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA

I. General Description

As specified more fully below, Elan shall retain an Independent Review Organization (IRO) to perform reviews to assist Elan in assessing and evaluating its systems, processes, policies, procedures, and practices related to Government Pricing and Contracting Functions (as defined in Section II.C.4 of the CIA), its Medical Affairs and Materials Related Functions (as defined in Section II.C.5 of the CIA), and its funding of educational grants and healthcare related charitable contributions (as discussed below in Section III.A) (collectively "IRO Reviews"). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Elan may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If, during the term of the CIA, there are no material changes in Elan's systems, processes, policies, and procedures relating to Government Pricing and Contracting Functions or to Medical Affairs and Materials Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Elan materially changes its systems, processes, policies, and procedures relating to Government Pricing and Contracting Functions or to Medical Affairs or Materials Related Functions, the IRO shall perform a Systems Review for the materially changed Function for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. Systems Review

The Systems Review shall be a review of Elan's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Government Pricing and Contracting Functions and to certain Medical Affairs and Materials Related Functions. Where practical, Elan personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The

IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Elan pursuant to the preceding sentence.

A. Systems Review - Part 1 (relating to Government Pricing and Contracting Functions)

The IRO shall review Elan's systems, processes, policies, and procedures (including the controls on the systems, processes, policies, and procedures) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating and reporting Average Manufacturer Price (AMP), Best Price, and Average Sales Price (ASP) to CMS (known as "Reviewed Policies and Procedures"). More specifically, the IRO shall review the following for Elan's Government Reimbursed Products as defined in Section II.C.3 of the CIA.

1. The systems, processes, policies, and procedures used to determine which Elan customers are included or excluded for purposes of determining AMP, BP, and ASP;

2. The systems, policies, processes, and procedures used to determine whether and which particular transactions (discounts, rebates) are included in or excluded from AMP, BP, and ASP determinations;

3. A review of Elan's methodology for applying transactions to the AMP, BP, and ASP determinations;

4. A review of Elan' s methodology for estimating any prices, discounts, or other amounts used in determining AMP, BP, and ASP;

5. The flow of data and information by which price, contract terms, and transactions with Elan customers are accumulated from the source systems and entered and tracked in Elan's information systems for purposes of determining AMP, BP, and ASP;

6. A review of any Elan inquiries to CMS regarding AMP, BP, and ASP determinations and reporting requirements, including requests for interpretation or guidance, and any responses to those inquiries; and

7. The controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations,

exceptions, or outliers). This shall include a review of the bases upon which variations, exceptions, and outliers are identified and the follow-up actions undertaken to identify the cause of any variations.

B. Systems Review - Part 2 (relating to Medical Affairs Related Functions)

The IRO shall review Elan's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to the following Medical Affairs and Materials Related Functions (known as "Reviewed Policies and Procedures"):

1. Elan's systems, policies, processes, and procedures applicable to the manner in which Elan representatives (including Medical Affairs personnel, Clinical Science Liaisons (CSLs), and/or headquarters personnel) handle requests for information or inquiries about the uses of Government Reimbursed Products in the United States (including the off-label uses of the products) and any dissemination of materials relating to the uses of such products in the United States.

   This review includes:

   a. the manner in which CSLs and headquarters personnel (including Medical Affairs personnel) with responsibility for the U.S. market receive and respond to requests for information about the uses of Government Reimbursed Products, including any off-label uses of such products;

   b. the form and content of product-related information disseminated by Elan or its agents to U.S.-based HCPs or U.S.-based HCIs;

   c. Elan's internal review and approval process relating to materials and information about Elan's products that Elan personnel disseminate to HCPs or HCIs in the U.S, including reviews that occur through review committee process;

   d. Elan's systems, processes, and procedures (including the Inquiries Database) to track requests from U.S.-based HCPs, HCI's or other persons for information about the uses of products in the U.S. and responses to those requests;

e. the manner in which Elan collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database;

f. systems, processes, policies, and procedures applicable to the functions of Elan's CSLs; the manner and circumstances under which CSLs or personnel from Elan's Medical Affairs group interact with or participate in meetings or events with HCPs or HCIs; and the role of such personnel at such meetings or events. This review shall include a review of any internal monitoring plan designed to monitor the activities of Medical Affairs personnel;

g. the processes and procedures by which the Chief Compliance Officer (and other appropriate individuals within Elan) identify and monitor situations in which it appears that improper promotion may have occurred in the United States; and

h. Elan's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion in the United States.

C. Systems Review Report.

The IRO shall prepare a report based upon both Parts 1 and 2 of each Systems Review.

For each of the topics identified in Section II.A above, the report shall include the following items:

1. A description of the methodology, systems, processes, policies, and practices in place to calculate, track, gather, and account for price terms, contract terms, and transactions with Elan customers that are relevant to the calculation and reporting of AMP, Best Price, and ASP, including, but not limited to:

   a. The computer or other relevant systems (including the source systems and any other information systems, as applicable) used

to track data for and to calculate and report AMP, Best Price, and ASP;

b. The information input into Elan's relevant computer or other systems used to calculate AMP, Best Price and ASP;

c. The system logic or decisional rationale used to determine which customers are included or excluded for purposes of calculating AMP, Best Price, and ASP;

d. The system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with Elan customers are included or excluded when calculating AMP, Best Price, and ASP; and

e. Elan's policies and practices in examining system reports for variations that require critical evaluation, including the basis on which variations, exceptions, or outliers are identified, and the follow up actions taken in response.

2. A description of the documentation, information, and systems reviewed, and the personnel interviewed, if any, including a description of the following:

   a. Elan's inquires to CMS or any State Medicaid program regarding the calculation of AMP, Best Price, and/or ASP and any responses to those inquiries;

   b. Elan's systems and practices for reporting AMP, Best Price, and ASP to CMS as required by the Medicaid Drug Rebate program and the Medicare Part B program; and

   c. Elan's systems and practices for reporting any adjustments or additional information related to the AMP, Best Price, and ASP submissions.

3. Observations, findings, and recommendations for any improvements to Elan's systems, processes, policies, and practices, including any changes recommended in order to improve compliance with the requirements of the Medicaid Program, the Medicaid Drug Rebate program, or the Medicare Part B program.

For each of the Reviewed Policies and Procedures identified in Section II.B above, the report shall include the following items:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;

2. a detailed description of Elan's systems, policies, processes, and procedures relating to the items identified in Section II. B above, including a general description of Elan's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section II.B.1 above are made known or disseminated within Elan;

4. a detailed description of any system(s) used to track and respond to requests and inquiries regarding off-label uses of Elan products;

5. findings and supporting rationale regarding any weaknesses in Elan's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

6. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. IRO Transactions Review

As described more fully below in Sections III.A-B, the Transactions Review shall include: (1) a review of Control Documents for a sample of external funding requests that were paid by Elan during the applicable Review Period for educational grants and healthcare related charitable contributions; and (2) a review of up to two additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. Review of External Funding Activities

1. Review of External Funding Activities

Elan has developed policies and procedures relating to its funding (direct and indirect) of educational grants and healthcare related charitable contributions. A healthcare-related charitable contribution is defined as a contribution provided to a healthcare organization or for a function that is related to healthcare.

For each Reporting Period, the IRO shall select and review a random sample of twenty percent of the total number of paid educational grants and charitable contributions or 25 grants and charitable contributions, whichever is a larger number, that were paid by Elan during the Reporting Period. For purposes of this review, the number of grants and charitable contributions to be reviewed by the IRO shall be in the same proportion as the overall number of grants and charitable contributions paid by Elan for the applicable Reporting Period.

2. Control Documents

For purposes of the IRO Review, the term "Control Documents" shall include all documents or electronic records (collectively "documents") associated with each funded educational grant and charitable contribution that are necessary to: 1) review and evaluate: the request for funding; 2) make an approval decision for the funding request; 3) ensure that the funding was used for the stated purpose (*e.g.*, an event to be funded by a charitable contribution actually occurred); and 4) ensure that work product generated in connection with the grant or charitable contribution was collected and used for intended purpose. For example, Control Documents could include, but would not be limited to, funding request letters, grant applications, business rationale forms, written contracts relating to the grant or charitable contribution, budget information, documentation that the event funded by the grant or contribution occurred, and documents reflecting any work product generated as a result of the funding. Each set of Control Documents relating to a particular educational grant or charitable contribution shall be referred to as a Sample Unit.

3. Review of Reviewed Activities Control Documents

For each Sample Unit, the IRO shall review the Control Documents to determine:

a. whether all required Control Documents associated with the educational grant or charitable contribution exist in appropriate files in accordance with Elan's policies;
b. whether all required Control Documents associated with the educational grant or charitable contribution were completed and archived in accordance with the requirements set forth in Elan's policies; and
c. whether the Control Documents associated with the educational grant or charitable contribution reflect that all required written approvals were obtained in accordance with Elan's policies.

4. Identification of Material Errors and Additional Engagement

Any Sample Unit that does not satisfy the criteria set forth above in Section III.A.3 shall be considered an exception and shall be so denoted by the IRO. The IRO will consider a Control Document to have a Material Error if either of the following is identified:

a. all the appropriate and required Control Documents relating to a educational grant or charitable contribution do not exist and (i) no corrective action has been taken prior to the IRO review; or (ii) the IRO cannot confirm that Elan has otherwise followed its policies and procedures; or
b. information or data is omitted from key fields in the Control Documents that prevents the IRO from understanding the nature of the expenditure and/or assessing compliance with Elan's Policies and Procedures.

If the IRO finds any Material Errors, it shall conduct an Additional Engagement to review the expenditures or activities reflected in the erroneous Sample Unit. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel (*e.g.*, CSLs, other Medical Affairs personnel, or supervisors) to identify the root cause(s) of the errors.

B. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to two additional items for the IRO to review (hereafter "Additional Items".) No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Elan of the

nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Elan shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report as specified below in Section III.C.

Elan may propose to the OIG that its internal audit(s) and/or reviews be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Elan's internal audit work and monitoring activities to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Elan's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Elan's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Elan's request to permit its monitoring activities or internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Elan shall engage the IRO to perform the Review as outlined in this Section III.B

If the OIG agrees to permit certain of Elan's monitoring activities or internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Elan in its internal audits.

C. IRO Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. General Elements to Be Included in Report

    a. Review Objectives: A clear statement of the objectives intended

to be achieved by each part of the review;

b. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling units and universes utilized in performing the procedures for each sample reviewed; and

c. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2. Results to be Included in Report

The following results shall be included in each Transactions Review Report:

(Relating to the Review of External Funding Requests)

a. a description of each Sample Unit reviewed, the number of Sample Units reviewed for educational grants and for charitable contributions, and an identification of the types of Control Documents reviewed for each Sample Unit;

b. for each Sample Unit, the IRO shall state its findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all requirements set forth in the applicable Elan's policy; (iii) each Control Document reflects that Elan's policies were followed in connection with the underlying grant or charitable contribution (*e.g.*, all required approvals were obtained and any events funded by the monies occurred); and (iv) any disciplinary action was taken in those instances in which an Elan policy was not followed;

c. for each Sample Unit reviewed, the IRO shall identify and describe all exceptions discovered. The IRO shall describe those situations where corrective action was taken prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action. The IRO shall also describe the situations in which it attempted to confirm whether Elan otherwise followed its policies and procedures, and the steps undertaken by the IRO to make that determination;

d. if any Material Errors were discovered for any Sample Unit, the IRO shall describe the Material Error in detail and shall describe the Additional Engagement that it performed, including any interviews conducted. The IRO shall state its findings as to the root cause of each Material Error(s);

e. the findings and supporting rationale regarding any weaknesses in Elan's systems, processes, policies, and practices relating to the funding of educational grants or charitable contributions, if any; and

f. recommendations for improvement in Elan's systems, processes, policies, and practices relating to the funding of educational grants or charitable contributions, if any.

(Relating to the Additional Items Review)

g. for each Additional Item reviewed, a description of the review conducted;

h. for each Additional Item reviewed, the IRO's findings based on its review;

i. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Elan's systems, processes; and

j. for each Additional Item reviewed, recommendations, if any, for changes in Elan's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.