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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SCIOS, INC., Defendant.	No. CR 11- 0461 CRB GOVERNMENT'S MEMORANDUM FOR ENTRY OF PLEA AND SENTENCING

I. INTRODUCTION

After many months of negotiations, the parties have reached a Plea Agreement in this case. An unsigned copy of the Plea Agreement has been provided to chambers. The Plea Agreement is an agreement under Rule 11(c)(1)(C) that contemplates a guilty plea to the filed Information and an $85 million fine. The parties are scheduled to appear before this Court for entry of plea on September 28, 2011. The parties urge the Court to accept the Plea Agreement and proceed immediately to sentencing.

II. THE INFORMATION AND PLEA AGREEMENT

A. The Information

On July 7, 2011, the United States filed a one-count Information charging Scios with a misdemeanor violation of 21 U.S.C. §§ 331(a) and 333(a)(1) by having caused the introduction and delivery for introduction into interstate commerce of the drug Natrecor that was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling lacked adequate directions for its use.

B. The Plea Agreement

The following are the key provisions in the Plea Agreement:

- Scios has agreed to plead guilty to the Information charging it with causing the introduction and delivery for introduction into interstate commerce of the drug Natrecor which was misbranded pursuant to 21 U.S.C. § 352(f)(1) because its labeling lacked adequate directions for use, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). *See* Plea Agreement, Paragraph 1.
- Scios has agreed that the Joint Factual Statement set forth as Attachment A to the Plea Agreement is a true and accurate statement of Scios's criminal conduct and that it provides a sufficient basis for its guilty plea. *See* Plea Agreement, Paragraph 2.
- Scios has agreed to pay a total monetary assessment of $85,000,125, which is comprised of a criminal fine of $85 million and a mandatory special assessment of $125. Scios shall make payment of the criminal fine within 7 business days from the date of sentencing and shall pay the special assessment of $125 at the time of sentencing. *See* Plea Agreement,

Paragraphs 6a & 6b. The parties also agree that the fine of $85 million is authorized by 18 U.S.C. § 3571(d). *Id*. at 6a.

- Scios has agreed to be placed on organizational probation for a period of three (3) years from the date of sentencing pursuant to 18 U.S.C. § 3561(c)(1) and U.S.S.G. §§ 8D1.1 and 8D1.2. *See* Plea Agreement, Paragraph 6d.
- The United States has agreed not to criminally prosecute Scios or its parent company, Johnson & Johnson, Inc., for any other offenses under the Food, Drug and Cosmetic Act (FDCA) or any other non-tax offenses related to the marketing and sale of Natrecor committed before the date of the Plea Agreement, and which were known to the United States at the time it signed the Plea Agreement. This waiver, however, does not apply to any civil or administrative actions, sanctions, or penalties that may apply, including, but not limited to, any False Claims Act liability. *See* Plea Agreement, Paragraph 10. Accordingly, the Plea Agreement does not waive or release any of the claims asserted by the United States in the pending False Claims Act case against Scios and Johnson & Johnson relating to the marketing and sale of Natrecor (*United States ex rel. Strom v. Scios, Inc. and Johnson & Johnson*, No. C 05-3004 CRB).

III. THE LEGAL FRAMEWORK GOVERNING THE CRIMINAL CHARGE

The applicable FDCA statutory provisions and implementing regulations material to this case have not changed since the time of the activity described in the Information. Pursuant to those provisions and regulations, a drug company is prohibited from distributing any new drug in interstate commerce until the company has received approval from FDA to distribute the drug for a specific use or uses. Such approval is based on an intensive application and review process. 21 U.S.C. § 355. The FDCA requires that a company submit a New Drug Application ("NDA") to FDA, which identifies all of the uses of the drug intended by the company, together with the company's proposed labeling for those intended uses and data, generated by well-controlled clinical trials, that demonstrate to FDA's satisfaction that the drug will be safe and effective for those intended uses. 21 U.S.C. § 355(b). Until FDA finds sufficient evidence of the drug's safety and efficacy for the uses intended by the company and approves the NDA,

including the proposed labeling for the drug, the FDCA prohibits the company from promoting or marketing the drug. 21 U.S.C. §§ 331(d) and 355(a).

The use of a drug not approved by the FDA, and not included in the drug's approved labeling, is known as an "unapproved use" or "off-label use." A drug company cannot lawfully promote an unapproved or off-label use of an approved drug. Rather, the company is first required to submit an application to the FDA for approval of the additional use, providing evidence, in the form of well-controlled clinical studies, sufficient to demonstrate that the drug is safe and effective for the additional use.

The FDCA prohibits the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of any misbranded drug. 21 U.S.C. § 331(a). Under the FDCA, a drug is deemed to be "misbranded" if its "labeling" does not contain "adequate directions for use." 21 U.S.C. § 352(f)(1).[1] The term "adequate directions for use" means directions under which a layperson can use a drug safely and effectively for the purposes for which it is intended. *See* 21 C.F.R. § 201.5. By definition, a prescription drug like Natrecor cannot bear adequate directions for use by a layperson. However, an FDA-approved prescription drug, bearing the FDA-approved labeling, is exempted from the "adequate directions for use" requirement *if and only if* its intended use is the FDA-approved use. 21 C.F.R. §§ 201.100 & 201.115. "Intended use" refers to the objective intent of the drug manufacturer because it is legally responsible for the labeling of its drug. 21 C.F.R. § 201.128. The exemption does not apply if the drug company markets the prescription drug for an unapproved use because such marketing demonstrates that one of the company's "intended uses" is an unapproved use. In sum, a drug company's marketing of the off-label use of its prescription drug causes a drug to be misbranded because the exemption to the statutory "adequate directions for use" requirement no longer applies. *See* 21 C.F.R. §§ 201.5, 201.100.

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[1] Under the FDCA, "labeling" means "all labels and other written, printed, or graphic matter" (1) placed on the drug or its container or wrapper, or (2) accompanying the drug. 21 U.S.C. § 321(m). Although no physical attachment of the labeling to the drug is necessary, the FDA-approved labeling for a drug is often included in or attached to its container or packaging.

The FDCA sets forth a two-tiered approach to criminal liability: violations committed with an intent to defraud or mislead, or following a prior conviction, are punished as felonies. All other violations are treated as misdemeanors. See 21 U.S.C. § 333(a) (1) and (2). Here, the United States has charged Scios with a misdemeanor FDCA misbranding violation and, as discussed below, Scios has stipulated to the essential elements of that charge.

IV. THE BASIS FOR THE PLEA AND SENTENCE

In the Joint Factual Statement attached to the Plea Agreement, Scios has admitted the essential facts giving rise to the FDCA violation. Scios has admitted:

- Scios was a publicly traded company with its principal place of business in the Northern District of California[2] and was engaged in the development, promotion, and sale of Natrecor, which was a prescription drug with the generic name nesiritide. *See* Joint Factual Statement, Paragraph 1. *See also* Plea Agreement, Paragraph 1a.
- Natrecor was manufactured in Kansas and shipped to other states, including California, from Kansas. *See* Joint Factual Statement, Paragraph 6. *See also* Plea Agreement, Paragraph 1c.
- Natrecor is a prescription drug as described in 21 U.S.C. § 353(b). *See* Joint Factual Statement, Paragraph 7. It is a vasodilator, that is, it opens the blood vessels and reduces filling pressure in the heart, and is administered intravenously to patients. *See* Joint Factual Statement, Paragraph 10.
- In August 2001, FDA approved Natrecor solely for the treatment of patients experiencing acutely decompensated heart failure ("ADHF") with dyspnea (shortness of breath) at rest or with minimal activity. The FDA-approved labeling for Natrecor did not list any other use of the drug, and the drug has never been approved by FDA for any other use. *See* Joint Factual Statement, Paragraph 11.
- Some patients with congestive heart failure ("CHF") experience ADHF. CHF is a medical condition in which the heart does not work as efficiently as it should and cannot

[2] It is the Government's understanding that, although Scios is still an existing corporation, it no longer markets Natrecor or actively conducts any other business operations.

pump enough blood to the body's other organs. *See* Joint Factual Statement, Paragraph 9.

- Infusing chronic (non-acute) CHF patients with Natrecor on a scheduled or serial basis was an unapproved, off-label use of the drug. The FDA-approved labeling for Natrecor did not contain any directions for this use of Natrecor. *See* Joint Factual Statement, Paragraph 12.
- Scios understood that the approved use of Natrecor for treating ADHF did not include infusing chronic (non-acute) CHF patients with Natrecor on a scheduled or serial basis. *See* Joint Factual Statement, Paragraph 13.
- One of Scios's "intended uses" of Natrecor was for infusing chronic (non-acute) CHF patients on a schedule or serial basis. This misbranded the drug, in that its labeling lacked adequate directions for use. *See* Joint Factual Statement, Paragraph 14. *See also* Plea Agreement, Paragraph 1b.
- Scios committed the unlawful conduct – that is, it caused the introduction and delivery for introduction into interstate commerce of a misbranded drug – between August 2001 and April 1, 2003.[3] *See* Joint Factual Statement, Paragraph 14.[4] *See also* Plea Agreement, Paragraph 1c.

As the Court is aware, there is a related civil proceeding: *United States ex rel. Strom v. Scios, Inc. and Johnson & Johnson*, No. C 05-3004 CRB, which is a matter of ongoing litigation before this Court. The allegations concerning Scios's "Scheme to Market Natrecor For Serial

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[3] In or around April 2003, Scios was purchased by Johnson & Johnson, subsequently merged with a Johnson & Johnson subsidiary on or about April 28, 2003, and thereby became part of J&J's Biopharmaceutical Group. After the merger, Scios ceased filing reports as a publicly traded company.

[4] The parties disagree about whether Scios's unlawful conduct continued after April 1, 2003. In the Information, the United States alleges that the unlawful conduct continued to at least June 2005. Scios maintains that the conduct did not occur after April 1, 2003. *See* Joint Factual Statement, Paragraph 14. This disagreement, however, does not need to be resolved for purposes of the Court's acceptance of the Plea Agreement. The parties agree that Scios's plea will be limited to reflect relevant conduct occurring during the August 2001 to April 1, 2003 time period.

Outpatient Infusions" are detailed in the United States' Complaint in the related matter, which is attached as Exhibit 1, and support the Government's allegations in this case that Scios's intended use for Natrecor included using the drug to infuse chronic (non-acute) CHF patients on a scheduled or serial basis. (See ¶¶ 62 -74 of the Complaint).

V. THE CRIMINAL FINE AND PROBATION

A. The Criminal Fine

Scios and the United States have agreed that, pursuant to 18 U.S.C. § 3571(c) and (d), the maximum fine is either $200,000 or not more than twice the gross gain or loss resulting from the unlawful conduct. *See* Plea Agreement, Paragraph 4a.

The fine provisions of the United States Sentencing Guidelines do not apply to organizational defendants for misdemeanor violations of the FDCA. *See* U.S.S.G. §§ 8C2.1, 8C2.10. Criminal fines are governed by 18 U.S.C. §§ 3553 and 3572. Pursuant to 18 U.S.C. § 3553(b), where there are no applicable sentencing guidelines (such as in this case), the court should "have due regard for the relationship of the sentence imposed to sentences prescribed by guidelines applicable to similar offenses and offenders." Moreover, pursuant to 18 U.S.C. § 3572(a), when determining the amount of an appropriate fine, a court should consider, among other things, the defendant's income and financial resources; the burden the fine would impose on the defendant; pecuniary loss on others inflicted by the offense; the need to deprive the defendant of pecuniary gains resulting from the offense; and whether the defendant can pass on to consumers or others the expense of a fine. 18 U.S.C. § 3572(a).

The parties have agreed that a fine of $85 million is authorized by 18 U.S.C. § 3571(d). *Id.* at 6a. Here, the $85 million fine is derived from the defendant's pecuniary gain from the offense. It is an appropriate penalty given the income, financial resources, and earning capacity of Scios and its parent company, Johnson & Johnson; the limited burden such fine places on Scios and Johnson & Johnson; and the need to deprive Scios of illegally obtained gains from the offense. Moreover, the fine both reflects the seriousness of the offense and provides adequate deterrence. This fine is also consistent with fines prescribed by the United States Sentencing Guidelines for similar offenses and offenders.

B. Probation

The authorized term of probation for a misdemeanor is not more than five years. 18 U.S.C. § 3561(c)(2). Scios agreed to be placed on organizational probation for a period of three years from the date of sentencing pursuant to 18 U.S.C. § 3561(c)(2) and U.S.S.G. §§ 8D1.1 and 8D1.2. *See* Plea Agreement, Paragraph 6d. The United States deems this probationary period to be sufficient based on an analysis of the factors set forth at 18 U.S.C. § 3553(a) (such an analysis being required by 18 U.S.C. § 3562(a)). It is the Government's understanding that Scios no longer actively markets Natrecor for any use, including its FDA approved-use, and that it no longer markets any other drug products. But, because the offense which Scios committed is serious and to protect the public, there is some need for probation to ensure Scios's compliance with the FDCA and other laws if it resumes marketing Natrecor or markets another drug product.

VI. VICTIMS AND RESTITUTION

The Crime Victims Rights Act ("CVRA") provides certain procedural and substantive rights to victims in criminal cases. To qualify as a "victim" under the CVRA, a person must be "directly and proximately harmed as a result of the commission of a Federal offense . . . ." 18 U.S.C. § 3771(e). The harm must result from "conduct underlying an element of the offense of conviction." *United States v. Blake*, 81 F.3d 498, 506 (4th Cir. 1996) (discussing the Victim and Witness Protection Act).

Here, the offense of misbranding as charged in the Information is not premised on direct and proximate harm to a victim as defined in the CVRA.[5] The Information charges that Natrecor was misbranded because Scios intended that it be used for a purpose other than the use approved by FDA. The harm at issue is that Scios's off-label promotion of Natrecor undermined FDA's drug approval process and that promotion for unapproved uses can interfere with the proper treatment of a patient. For example, off-label promotion can lull a physician into believing both that the

[5] Two other victim rights' statutes – the Victim and Witness Protection Act, 18 U.S.C. § 3663 (VWPA), and the Mandatory Victims Restitution Act, 18 U.S.C. § 3663A (MVRA), are not directly applicable in this case because the misbranding offense to which Scios is pleading guilty is not covered by these statutes. Consequently, there are no available avenues for restitution for alleged victims under the VWPA or the MVRA.

drug being promoted is safe and effective for the intended off-label use and that FDA has approved the drug for that use.

The crime of misbranding is, however, complete regardless of the success of the company's promotional efforts. The offense is established by proof that Scios caused the introduction or delivery for introduction into interstate commerce of a misbranded drug. While an individual may allege direct harm from the use of Natrecor in another forum, a variety of potential intervening factors renders any harm to a person taking Natrecor too attenuated in the context of a criminal misbranding case for such a person to qualify as a victim under the CVRA. *See In re: Jane Doe*, 264 Fed. Appx. 260, 263 (4th Cir. 2007) (unpublished) (misbranding case holding that consumer of Oxycontin was not a victim for purposes of restitution within the meaning of the Victim and Witness Protection Act where there was no evidence that her injuries flowed directly and proximately from the misbranding); *see also United States v. Kones*, 77 F.3d 66, 69, 71 (3rd Cir. 1996) (holding that patient was not a "victim" within the meaning of the Victim and Witness Protection Act of defendant-doctor's scheme to submit false insurance claims).

In addition, although the Court has the authority to order restitution as a condition of probation (*see* 18 U.S.C. § 3563(b)(2)), or supervised release (*see* 18 U.S.C. § 3583(d)), and pursuant to U.S.S.G. § 5E1.1(a), the Court may decline to impose an order of restitution if it determines that the complication and prolongation of the sentencing process resulting from fashioning an order of restitution outweighs the need for restitution. *See* 18 U.S.C. §§ 3663(a)(1)(B)(ii), 3663A(c)(3)(B); *see also* U.S.S.G. § 5E1.1(b)(2). The United States and Scios have agreed that, in this matter, the complication and prolongation of the sentencing process resulting from fashioning any order of restitution would outweigh the need to provide restitution to victims (other than federal program payors). *See* Plea Agreement, Paragraph 6c.

In a misbranding case such as this, determining whether an individual or non-government payor was actually victimized by the defendant's conduct, and the harm resulting therefrom, is a complex and very time-consuming process. First, it would be extraordinarily difficult for the United States to identify potential individual victims or non-government payor victims and notify them about this matter given that the conduct to which Scios will plea occurred more than

eight years ago. Second, even if the United States could identify any potential victims, validating a claim of restitution would involve detailed factual determinations about harm and causation and amount of loss.

Furthermore, the need to provide restitution to individuals and non-government payors does not appear significant here. Government payors, especially the Medicare Program, paid for a substantial amount of the off-label use of Natrecor. The United States is unaware of any non-government payors who have sought to recover from Scios payments they made for the off-label use of the drug. At this time, the United States is also unaware of any reports of patients who suffered actual physical harm due to the off-label use of the drug. Accordingly, the complication and prolongation of the sentencing process resulting from attempting to fashion restitution would outweigh the need to provide restitution to individuals and non-government payors in this case.

The United States and Scios also agree that there should be no restitution ordered to federal program payors through this criminal action because of the pending civil False Claim Act claims brought by the United States against Scios and its parent company, Johnson & Johnson, in *United States ex rel. Strom v. Scios, Inc. et al*., CV 05-3004 CRB (NDCA). *See* Plea Agreement, Paragraph 6c. In that civil action, if the United States prevails, it is entitled to recover treble damages plus penalties for losses incurred by federal program payors due to the defendants' violations of the False Claims Act arising from their promotion of the off-label use of Natrecor.

VII. CONCLUSION

For the reasons discussed above, the criminal resolution reached by the parties takes into account the nature and seriousness of the offense and the agreed-upon sentence is appropriate in this case. This resolution will promote respect for FDA's regulatory process for reviewing and approving drugs and will deter circumvention of that process. The agreed-upon fine also provides just punishment for the offense committed. Accordingly, the United States respectfully requests that the Court accept Scios's plea and enter the agreed-upon sentence set forth in the Plea Agreement.

Dated: _____ Respectfully submitted,

JOSHUA B. EATON
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/s/
_____
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