UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	**Criminal No.: 09-CR-10035-DPW**
v.	
SHANE DOYLE,	
Defendant.	

AGREED STATEMENT OF FACTS

The United States of America, by and through its counsel, and defendant Shane Doyle, individually and by and through his counsel, respectfully submit the following agreed statement of facts in connection with the plea hearing in United States v. Shane Doyle, 09-CR-10035-DPW. Mr. Doyle acknowledges that the following is a true account of his conduct in connection with the crime charged in the Information.

From mid-2002 through approximately August 2007, Mr. Doyle was employed as a territory manager by a corporation based in Hopkinton, Massachusetts, and referred to in the Information as XYZ Corporation, that manufactured and sold certain medical devices, including medical devices for use in healing of fractured or broken bones. These medical devices included the following: (a) a device, referred to herein as Device-A, which was an implant to promote growth in certain long bone non-unions; (b) a device, referred to herein as Device-B, which was a putty to promote bone growth in certain spinal fusions; and (c) a device, referred to herein, as Device-C, which was a bone void filler for surgically created osseous defects or osseous defects resulting from traumatic injury.

Each of Device-A, Device-B and Device C was a medical device within the meaning of the Federal Food, Drug and Cosmetic Act, and as such was regulated by the United States Food & Drug Administration ("FDA"). In response to prior applications submitted to the FDA by XYZ, by mid-2004, the FDA had granted each of Device-A and Device-B a Humanitarian Device Exemption ("HDE"). The HDE for Device-A was only for "use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed." The HDE for Device-B was only for "use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion."

Also, in mid-2004, the FDA, in response to XYZ's premarket notification of intent to market a bone void filler product, notified XYZ that it could market the device, referred to herein as Device-C, as indicated as "a bone filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury."

Humanitarian Device Exemptions are for devices that fail to meet the effectiveness requirement for a premarket approval, but meet certain other requirements, such as safety. HDEs impose a number of restrictions on the holder of the HDE. For starters, HDEs are for medical devices designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States. The holder of an HDE is prohibited from selling the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. Also, by statute, HDEs may only be used in facilities that have established a local

institutional review board, known as an IRB, which must approve the device before its use.

XYZ has never applied to the FDA for use of Device-B in conjunction with or mixed with Device-C, nor has the FDA ever approved any such use. From approximately February 2006 through at least July 2007, Mr. Doyle, in his capacity as a territory manager, and others at XYZ promoted the sale and use of Device-B to be mixed with and used in conjunction with Device-C. Mr. Doyle and others at XYZ on occasion did so affirmatively and without a solicitation or question from the surgeon or the surgical staff. The use of Device-B to be mixed with and used in conjunction with Device-C was an unapproved use.

One of the means by which Mr. Doyle and others at XYZ promoted this unapproved use was to prepare and/or distribute to others (including surgeons, surgical staff, XYZ colleagues, or employees of XYZ affiliates) "mixing instructions." One set of mixing instructions used by Mr. Doyle was a so-called "dry-mix" and directed the user to combine all of the dry powder from the Device-C and the Device-B and then add only the amount of saline directed by the Device-C label. On May 16, 2007, Mr. Doyle provided these instructions in writing. These mixing instruction documents constituted labeling of the two products, and the labeling was false or misleading because neither Device-B nor Device-C was approved by the FDA for combined use.

Mr. Doyle's conduct caused the introduction into interstate commerce of a misbranded device, namely Device-B. Mr. Doyle's conduct satisfied the "intent to defraud or mislead" element of the offense in that at all material times, he was aware: (1) that neither Device-B nor Device-C was approved by the FDA for combined use; (2) that there was no randomized, well-controlled clinical data to support a combined use of Device-B and Device-C; and (3) that there had been adverse events in some patients in whom a mixture of Device-B and Device-C had

been implanted.

Based on these facts and evidence, which are only a portion of that which would be offered at trial, the United States would be able to prove beyond a reasonable doubt each of the elements of a violation of 21 U.S.C. §§331(a) and 333(a)(2) as charged in the Information.

For the United States of America:

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