UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	**Criminal No.** 1-10035 DPW
v.	**Violation:**
SHANE DOYLE,	**21 U.S.C. §§331(a), 333(a)(2) and 352 (distribution of a misbranded device)**
Defendant.	

INFORMATION

The United States Attorney charges that:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. **SHANE DOYLE** (hereinafter "**DOYLE**"), is an individual currently residing in Winchester, Massachusetts. From mid 2002 through approximately September 2007, **DOYLE** worked as a Territory Manager for a corporation hereinafter referred to as XYZ Corp ("XYZ"). XYZ was a corporation based in Hopkinton, Massachusetts engaged, *inter alia*, in the manufacture and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) Device-A, which was an implant to promote growth in certain long bone non-unions; (b) Device-B, which was a putty to promote bone

growth in certain spinal fusions; and (c) Device-C, which was a bone void filler for surgically created osseous defects or osseous defects resulting from traumatic injury.

2. The United States Food & Drug Administration ("FDA") was the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans were safe and effective for their intended uses and labeled accurately and in compliance with the law.

3. Device-A, Device-B and Device-C were medical devices within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §321(h).

4. On October 17, 2001, the FDA, in response to a prior application by XYZ, approved Device-A pursuant to a Humanitarian Device Exemption ("HDE"). The FDA approval 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."

5. On April 7, 2004, the FDA, in response to a prior application by XYZ, approved Device-B pursuant to an HDE. The FDA approval 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."

6. On August 26, 2004, the FDA, in response to a Section 510(k) premarket notification of intent to market a bone void filler product, notified XYZ that it could market the device (Device-C). Device-C was indicated as "a bone void 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."

7. XYZ has never applied to the FDA for use of Device-A in conjunction with or mixed with Device-C, nor has the FDA ever approved any such use.

8. 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.

9. At various times in 2007, **DOYLE** and others at XYZ Corp. promoted the sale and use of Device-A or Device-B to be mixed with and used in conjunction with Device-C. This was an unapproved use.

10. One of the means by which **DOYLE** and others promoted this unapproved use was to prepare and/or distribute "mixing instructions" to others (including surgeons, surgical staff, or employees of XYZ affiliates). There were a variety of mixing instructions used by **DOYLE** and XYZ. One set used affirmatively by **DOYLE** stated that "this could be printed out and put in the fridge with the OP-1 to make sure there are no questions on how to mix."

Count One:
21 U.S.C. §§331(a), 333(a)(2) & 352(f)(1) - (Distribution of a Misbranded Device)

11. The allegations contained in paragraphs 1 through 10 are realleged and incorporated herein as if set forth in full.

12. In or about May 2007, in the District of Massachusetts and elsewhere, the defendant,

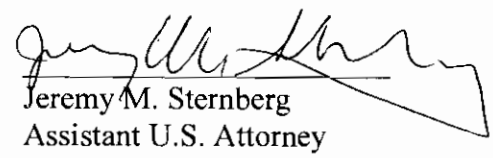
SHANE DOYLE,

with intent to defraud and mislead, did introduce and cause the introduction into interstate commerce, directly and indirectly, quantities of Device-B, a device within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321(h), in combination with Device-C, which was an unapproved use, and therefore misbranded within the meaning of 21 U.S.C.§352(f)(1), in that Device-B's labeling lacked adequate direction for such use.

All in violation of 21 U.S.C. §§331(a), 333(a)(2), and 352(f)(1).

Respectfully submitted,

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

By: 
Jeremy M. Sternberg
Assistant U.S. Attorney