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File No. 3455-0010

October 30, 2009

## **VIA E-MAIL AND REGULAR MAIL**

Ms. Jacqueline Collins  
Nobel Biocare USA, LLC  
22715 Savi Ranch Parkway  
Yorba Linda, California 92887

**Re: Implant Direct, LLC**

Dear Ms. Collins:

I am writing to you about the continuing problem of Nobel Biocare (“Nobel”) disseminating false and misleading information, harmful to Implant Direct’s reputation. In a mass mailing (October 29, 2009 - attached) by Mr. John Meredith, Western Regional Sales Manager for Nobel Biocare, Canada, Nobel falsely represents and suggests that a notice posted on Health Canada’s website involved a “significant recall” related to Implant Direct purportedly experiencing “sterility, packaging or product quality” issues.

**[Here is a link to the “Official Closure Notice” from Health Canada of Recall #50598](#)** which related to implants sold prior to September 2007 described on Health Canada’s website as having “cover caps (that) exhibited visible cracks post sterilization.” **[Nobel had been provided documentation to confirm that these micro-cracks were only cosmetic blemishes that did not effect the maintenance of sterility](#)** and that the recall only involved the exchange of seven implant vials.

It is rather disingenuous of Nobel to criticize Implant Direct’s packaging, sterility or quality control when Nobel is facing the possibility of a massive recall of all its products labeled as “sterile.” **[Nobel’s implants failed an independent dye leak test conducted by a FDA certified laboratory](#)**. Mr. Meredith’s email is a blatant attempt by Nobel to distract dentists from the potential risk that its own packaging compromises sterility. We had previously sought to avoid litigation by requesting that Nobel cease using false and

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misleading information about this minor voluntary recall as a method of competing with Implant Direct. These requests have apparently fallen on deaf ears.

On Wednesday, October 14, 2009, one of Nobel's sales managers sent an email to Josh Gibson, a Dental Solutions Specialist working for Nobel Biocare Canada Inc., about Health Canada's website posting regarding the Implant Direct voluntary recall #50598. This e-mail, in turn, was forwarded to some of Implant Direct's and Nobel's customers, who provided a copy of the e-mail to Implant Direct. Mr. Gibson's e-mail, like Mr. Meredith's e-mail, contains false statements and insinuations.

First, Mr. Gibson states the recall involves the "recall of a *substantial amount* of Implant Direct implants and accessories." (Italics added.) This is a false statement. The recall resulted in the recovery from Implant Direct customers of **seven implant vials** with micro-cracks in the vials – hardly a "substantial amount."

Second, Mr. Gibson states that the "quality issue appears to date back to August of 2007 and all of these vials should have been removed from inventory." This statement is misleading. It falsely suggests that cracked vials were *not* removed from Implant Direct's inventory when, in fact, all such vials (representing less than one percent of Implant Direct's inventory) were removed from inventory in August 2007 – a fact Health Canada does not dispute. The statement also falsely suggests that the "quality issue" has been *ongoing* since August 2007. Implant Direct fixed the problem in August 2007 and, thereafter, no cracked vials were manufactured after that date – another fact Health Canada does not dispute.

Health Canada accepted Implant Direct's report submitted on September 16, 2009 documenting the recovery of all implants and healing collars with white caps exhibiting the cosmetic micro-crack. Based on Implant Direct's test results provided to Health Canada confirming that its vials with the micro-crack feature passed extensive dye leak testing, Health Canada did not require Implant Direct to recall all of the products shipped in Canada between May through August 2007, but only those exhibiting the micro-crack, yielding only seven implant vials. The Health Canada Notice on its website states that doctors could contact Implant Direct to find out what lot numbers were affected, but Implant Direct proactively contacted all its Canadian customers who may have received such vials, and by September 16, 2009, had recovered all products with micro-cracks

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shipped prior to September 2007, eliminating any additional recall activity.


Dr. Niznick confronted Mr. Cox, Nobel Biocare's North American Sales manager, at the Toronto AAOMS meeting on October 16, 2009 about the dissemination of Mr. Gibson's false and misleading report and was told that it was not intended for circulation to doctors, only as a talking points memo. Apparently, Nobel thinks it is okay to provide its salespeople with false information to mislead dentists as long as they do not leave any written evidence. Subsequent to October 16, and in spite of the "resignation" of Mr. Mosher, VP of North American Sales, Nobel has conducted a Canada-wide campaign of disinformation, indicating exactly how desperate Nobel is to stem the loss of its customers to Implant Direct.

Implant Direct cannot help but notice the direct relationship between the accelerated, negative activity of Nobel's employees, attempting to discredit Implant Direct over its very limited packaging recall, and the increased concerns by dental professionals and stock analysts, about Nobel Biocare's packaging issues. While Nobel is quick to point out a voluntary Canadian recall conducted by Implant Direct, it does not disclose to its customers that during the same period, Nobel was experiencing its own Health Canada Recall #48621. On a far more serious note, [a Stock Analyst's Report](#) references test results from an independent FDA certified laboratory submitted to the FDA, showing that Nobel's products labeled as "sterile" and claiming a five year shelf life failed seal integrity tests.

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Implant Direct demands that Nobel (1) cease and desist its continuing practice of disseminating false and misleading information about this matter, and (2) immediately send out a corrective e-mail to its sales force confirming that (a) Implant Direct discovered and corrected the problem regarding the cracked vials in August 2007, at which time it removed all cracked vials from its inventory, and (b) the recall did not involve a substantial amount of Implant Direct implants and accessories and, in fact, involved only *seven* cracked vials, all of which were recovered. This is Implant Direct's last warning.

Very truly yours,

A handwritten signature in black ink, appearing to read "D. Gottesman", with a long horizontal flourish extending to the right.

Donald S. Gottesman