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Our Ref: EMcG

Your Ref:

8th May 2012

Dr. Tony Holohan Chief Medical Officer Department of Health Hawkins St. Dublin 2

Fax: 6710148

Re: PIP Breast Implants

Dear Dr. Holohan,

We write this as an open letter to you and will put it on our website.

1. Representation

We are instructed by a number of women that have been fitted with defective breast implants manufactured by Poly Implant Prothèses (PIP) and in connection with their claims for personal injuries suffered arising therefrom.

Our clients, generally, consider that the injuries occurred through breach of duty of the hospitals/clinics whereby they were fitted with those defective implants.

We note that you are in discussion with the said hospitals/clinics on the same issue (we expect). Consequently, we write to ask that you keep us informed of the details of those discussions and to seek our suggestions on the form of any proposals advanced by the state to the hospitals or our comments on any proposals advanced by the hospitals.

We would be particularly pleased for a briefing on the current position.

We say this in the light of the recent declaration of the Irish Medicines Board that independent clinics (not owned by the state), furnishing cosmetic surgical services, were and are beyond the regulation of the state.

We believe that statement not to be accurate, for several reasons.

As justification for our position we recite Section 11 of the Sale of Goods and Supply of Services Act 1980:

"11.—(1) Subsections (2) and (3) apply to any statement likely to be taken as indicating that a right or the exercise of a right conferred by, or a liability arising by virtue of, section 12, 13, 14 or 15 of the Act of 1893 is restricted or excluded

otherwise than under section 55 of that Act.

- (2) It shall be an offence for a person in the course of a business to do any of the following things in relation to a statement to which subsection (1) refers:
- (a) to display on any part of any premises a notice that includes any such statement, or
- (b) to publish or cause to be published an advertisement which contains any such statement, or
- (c) to supply goods bearing, or goods in a container bearing, any such statement, or
- (d) otherwise to furnish or to cause to be furnished a document including any such statement.
- (3) For the purposes of this section a statement to the effect that goods will not be exchanged, or that money will not be refunded, or that only credit notes will be given for goods returned, shall be treated as a statement to which subsection (1) refers unless it is so clearly qualified that it cannot be construed as applicable in circumstances in which the buyer may be seeking to exercise a right conferred by any provision of a section mentioned in subsection (1)."

It is our clients' consistent position that the PIP breast implants are defective and therefore not merchantable and therefore their supply by the hospitals was in breach of Section 14 of the 1980 Act.

That being the case, refusals by the hospitals, in writing, even to you, to replace the implants or to refund our clients' costs of their implantation are, we believe, in criminal breach of Section 11 of the Sale of Goods and Supply of Services Act 1980. In the event that you are in possession of evidence of such we urge you to refer the evidence to the Director of Consumer Affairs for prosecution.

You will notice that the 1980 Act mandates replacement of defective goods, not just their "recall".

We urge you therefore, not to discuss any proposals from the hospitals, limited to removal as opposed to replacement. To do otherwise would be to undermine our clients' statutory rights.

2. Injuries and loss

We should like to give you a brief insight into the consequences of the fitting of these implants.

Currently, we can only summarise, under broad heads, the nature of our clients' claims.

(1) General damages

Our clients have suffered personal injury, of varying degrees. They have the prospect of a surgical operation to remove the implants or, in some cases, have already undergone the operation. Some have suffered rupture of the implants; all,

we believe, suffer from seepage. This is, however, just a summary and should not be regarded as a comprehensive description of the injuries pending receipt of expert medical opinion.

They all are victims of breach of contract.

(2) Expenses and losses

We expect the claim for expenses and losses will include the following heads.

- (i) Refund of the cost of implantation;
- (ii) Recovery of the cost of removal and replacement;
- (iii) Medical expenses;
- (iv) Loss of earnings;

Further details would relate to individual cases and are not pertinent to this letter.

3. Conflicts of Interest

We wish to alert you to the inadvisability of referring claimants to the surgeons who performed the operations of implantation. Without wishing to impugn them in this letter, it is surely not appropriate that those surgeons should advise claimants?

There are many surgeons in Ireland qualified and available to give the necessary advice and, importantly, make the necessary assessments of the claimants' injuries and who have not been employed by the defendant hospitals in the supply of PIP implants.

We particularly advise against any proposal that the defendant hospitals should arrange the removal of the PIP breast implants.

We look forward to receiving your response to this letter.

Yours faithfully,

McGarr Solicitors