

## Response to “Banning Textured Implants Is a Rational Decision to Eliminate the Risk of Breast Implant–Associated Anaplastic Large-Cell Lymphoma (BIA-ALCL)”

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We thank Drs Hall-Findlay and Swanson for their comments<sup>1</sup> on our article.<sup>2</sup> We would like to emphasize that nowhere in our report do we describe the decision to ban textured implants as irrational. The purpose of our study was to determine if there was sufficient evidence to support the banning of textured implants.

As the authors state, one of the greatest threats to the validity of any cost-effectiveness analysis (CEA) is the quality of the studies that are included in the analysis. We agree that the main limitations of our study are the age and quality of the randomized controlled trials included in the meta-analysis to determine the incidence of complications in textured and smooth implants. Many factors contributing to capsular contracture and late seroma were not known in the 1990s when most of the included studies were carried out; however, it is the best available evidence.

Some of the studies randomized patients and others randomized the treated breast; we dealt with that issue according to Cochrane Handbook suggestions. Although Drs Hall-Findlay and Swanson correctly state that in some of the studies the effect size was not sufficient to decide in favor of textured implants, in all of the studies the numbers favored textured implants, and in none did the results favor smooth implants; and that is exactly the purpose of a meta-analysis—to assist decisions based on small studies.<sup>2</sup>

The pooled capsular contracture rate for implants in a subglandular pocket was 41% in our analysis.<sup>2</sup> One of

the authors stated that their capsular contracture rate is much lower; however, we could not find any study authored by them that corroborates this. It is interesting that when we compare capsular contracture rate differences in the Allergan, Mentor, and Sientra studies between smooth and textured implants, capsular contracture rates in those studies lie within the 95% confidence interval calculated in our meta-analysis, adding robustness to our assumptions.<sup>2</sup>

We agree again that most of the current evidence about breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL) etiology and its relation with roughness is level V evidence, and although it seems biologically plausible, there is no level I or II evidence that proves a connection. As a scientific community we should be concerned about any low-quality evidence used to sustain our decisions and we should demand proper randomized controlled trials

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from industry with adequate long-term follow-up based on standardized outcomes in order to incorporate new devices.

The risk of BIA-ALCL of 1 in 16,909 was intermediate between the risks of 1 in 3000 and 1 in 30,000 published in the literature. Now we know that Biocell implants have a higher risk (1 in 2200). Our sensitivity analysis showed that if the probability of developing BIA-ALCL is higher than 1 in 12,500, the number of life years gained becomes effective for smooth implants.

We think the authors may have misunderstood the concept of a CEA. The purpose of a CEA is not to put a value on human life; on the contrary, they are undertaken to look for interventions that will save the greatest number of lives possible for the same amount of money. Our cutoff points were not chosen lightly; we adhered strictly to World Bank recommendations. We completely agree about the devastating impact that cancer has on a patient. As Drs Hall-Findlay and Swanson state, there are many issues about contracting BIA-ALCL that cannot be measured, such as psychological discomfort and physical mutilation from cancer surgery, that will lead to poor quality of life; but this statement is valid for both sides. To avoid 1 case of BIA-ALCL, 2925 reoperations because of capsular contracture will be performed.<sup>2</sup> These 2925 women will also face disfigurement, pain, sexual impairment, and many other problems that will harm their quality of life. Whether the sufferings of 2925 women outbalance the suffering of 1 woman with BIA-ALCL is not ours to decide, but we think it is important to lay all the cards on the table before making a decision as a scientific community. The 2925 reoperations have inherent risks that also include death.

Finally, none of the authors of this CEA has any financial interest in any breast implant company, none of us speaks for any breast implant company, most of us use several implant brands according to surgeon/patient preferences, and indeed this study was made with the objective of helping with decision-making in order to improve patient safety. We again thank Drs Hall-Findlay and Swanson for their comments, and we hope sincerely that a new generation of microtextured implants may be able to reduce the risk of BIA-ALCL as well as the risk of capsular contracture.

## Disclosures

Dr Danilla has received airplane tickets, lodging, and inscription costs for medical congress assistance from Polytech. Dr Albornoz has received travel expenses from Allergan for a medical conference. Dr Erazo has received airplane tickets from Allergan and Polytech. The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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