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Authors' response



We read with interest these 2 separate correspondences, both authored by employees of Aimmune Therapeutics.^{1,2} We certainly appreciate their interest in our qualitative research study about motivations for seeking peanut allergy therapy.³ With the potential approval of 2 drugs to help treat peanut allergy in the next year, this is a timely topic. Both queries highlight alleged problems regarding our methods and conclusion and voice rather fervent, somewhat misplaced, comments and inappropriate posturing regarding Aimmune's interpretation of DBV's topline data for their phase 3 trial.⁴ These pieces also read as a curious disapproval of this work based on their perception that our findings are biased toward a particular product. It should have been obvious that the brief description of both trials was simply background context; otherwise, that section of our article has no pertinence to our project. We discuss only the study participant—described motivations for seeking therapy, ascertained through our qualitative interviews, and do not make any conclusions or speculations about how these may fit a particular product. Thus, any associations or judgments made about the quotes and themes presented and how these may relate to particular products are Aimmune's alone not ours. This is quite clear given we made no such statements or judgments in our article.

There is some difficulty in understanding precisely the point these correspondences are trying to make. A common theme of both is a distracting and entirely nonsequitur argument about the product phase 3 trial and results, which are immaterial to our study aim and methods. Their strong criticism of the trial outcomes of a perceived rival developing their own product is unwarranted in this forum, particularly given that our study explored motivations for seeking therapy not satisfaction with phase 3 trials results. Therefore, we leave it to the reader to decide what the outcome of our conclusions may or

may not imply regarding a specific product. Each reader can weigh the issues that Aimmune raises in light of forthcoming published phase 3 trial data for both products. The correspondence authors accurately identify a typographical error in our introduction, which was detected in the early-view manuscript version beneath the clearly identified watermark of uncorrected proof before the galley proof was available to us and then corrected.

It is difficult to address the specific methodologic criticisms waged, given that they are steeped in significant misunderstanding of qualitative research and methods and how this differs from quantitative or market research. This is not the forum to discuss such differences, and we included references for the sound qualitative methods we followed in our article.^{5,6} I will briefly address 2 points raised. First, qualitative sampling does not aim for balance or stratifications customary in quantitative research. Instead, is based on the concept of purposeful sampling to achieve maximal variation regarding the experience being elicited, which continues not until some specific number of participants is reached but rather until thematic saturation is met (ie, when no new information is being obtained through the interviews).^{5,6} This is an iterative and fluid process, which to an inexperienced reader may feel more subjective and potentially biased compared with quantitative studies. However, when well-established qualitative methods are followed, as was done in our study, research into understanding questions related to experience and motivations can be explored.

Second, as we have noted, this study had nothing to do with the study participant's actual trial enrollment status. Our aims and hypothesis were not to perform comparative analysis of our findings among products or enrollees of different trials. Such a study would be quantitative not qualitative. Our focus was to understand the deeper themes, goals, and motivations of parents to consider seeking any peanut allergy treatment for their child. Despite Aimmune's concerns of the constituency of our sample, we found there was uniformity in the motivations and concerns expressed about therapy from caregivers of children enrolled in both trials that undermines the notion that such responses could be stratified by the participant's specific trial enrollment. As well, our purpose was not to ascertain caregiver alignment of their goals with the actual trial results (again, better answered with a quantitative study design). That said, Aimmune's concern raised here is surprising given that the goal of both of the phase 3 peanut allergy treatment trials were identical—desensitization to a small amount of peanut protein, albeit achieved through different mechanisms and with end points defined differently—by an eliciting dose that provokes objective symptoms in one trial and by the highest dose tolerated with no more than mild symptoms (but not the highest dose at which the patient was completely asymptomatic) in the other.^{4,7} The suggestions that our research participants were “likely suggestable,” were motivated to show us they were

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Disclaimer: Drs Sicherer and DunnGalvin were authors on the original article and were aware of the correspondences but were uninvolved in the formulation and content of this response and have given us written permission to not include them.

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“good participants,” or that our interview guide and consent language were biased and leading are completely without merit and unnecessarily impugn our group’s research motivations and capabilities. We would presume that semistructured interviewing was discussed in the references regarding qualitative methods that were listed in the correspondence by Matthews et al² and simply refer all interested readers to seek further clarification within those references on this well-established, basic facet of conducting a qualitative research study.^{8–10}

The Aimmune employees who have authored these commentaries are entitled to their own opinions, and as scientists, we are open to thoughtful critique of our research. However, such an approach begs the question of why someone would look a gift horse of free and potentially useful information in the mouth and why they have chosen to interpret the rather generic themes as somehow being in favor of epicutaneous immunotherapy and not oral immunotherapy. Again, this was not our conclusion, and no single participant interviewed elaborated such a conclusion—Aimmune has reached this on their own accord and furthermore appears to be attempting to discredit research findings that they perceive as potentially unfavorable. It is unfortunate that the focus here has been diverted away from what is important—what the patient may value in this new and developing area of therapy. One of the purposes of qualitative research is to illuminate perspectives that are not easily gained in other ways. To reiterate, we identified that parents of children with peanut allergy had the following perspectives: (1) parents are seeking a therapy that only needs to provide minimal protection with minimal risks and (2) such protection would enhance quality of life through potentially decreasing reaction severity and enhancing life activities. Understanding parents’ perspectives should be of paramount importance to any company manufacturing a treatment for the children of these parents. Therefore, by focusing on an incorrect concern that the article may cast aspersions on their treatment and on a since-corrected typographical error, they have missed an opportunity to learn the parents’ perspectives from this rigorous qualitative study.

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Pressure, trigger forces, and epinephrine auto-injectors



The recent article by Dreborg et al¹ concluded that Emerade, defined as a low-pressure epinephrine auto-injector, has no risk of intraosseous injection in children and a low risk of subcutaneous injection in adolescents and adults. However, assumptions leading to these conclusions could be incorrect.

In this study and its 3 source studies,^{2–4} there is no evidence demonstrating that Emerade has a lower trigger force than other epinephrine auto-injectors. The company website and product materials do not describe Emerade as low pressure or provide any information about pressure, trigger force, or tissue compression.⁵ There also is no information on the European Medicines Agency website or in the published literature.

In addition, this study and its source studies do not describe how the ultrasonographer reliably applied force. The study of infants weighing less than 15 kg by Kim et al³ and the study of adults by Tsai et al⁴ described that minimal or an estimated maximal force of 2 to 8 lb was applied. The study of 202 children by Dreborg et al² described that minimal or 8 lb of pressure was applied. Food and Drug Administration documents for Auvi-Q indicate that trigger forces are 2 to 10 lb compared with 2 to 8 lb for EpiPen.⁶ Thus, the investigators frequently used the high-end trigger force range of these devices. Average trigger force is 6 lb for Auvi-Q (personal communication). Average trigger force for EpiPen was unavailable on request.

Force and pressure differ. Force is applied to the entire device, whereas pressure is the force per unit area over which that force is distributed. Hence, an 8-lb force applied to a rectangular ultrasound

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