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# Impact of Acne Vulgaris and Sarecycline on Social/Emotional Functioning and Daily Activities: PROSES Study

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# ABSTRACT

Background: Concise patient-reported outcome (PRO) instruments addressing the consequences of facial acne vulgaris (AV) on patients' functioning and activities of daily living (ADL) are needed.

**Methods:** A 12-week, single-arm, prospective cohort study was conducted in patients  $\geq$ 9 years old with moderate/severe non-nodular facial AV prescribed sarecycline as part of usual care. The primary endpoint included AV-specific patient- and caregiver-reported outcomes assessed with the expert panel questionnaire (EPQ, developed by 10 experts using a Delphi method) in patients (>12 years) and caregivers (for patients 9-11 years). Additional assessments included parental/caregiver perspectives on children's AV.

**Results:** A total of 253 patients completed the study. Following 12-weeks of treatment, there were significant ( $P \le .0001$ ) changes from baseline in the proportion of patients responding that they never or rarely: felt angry (31.6%), worried about AV worsening (28.9%), had thoughts about AV (20.9%), had a certain level of worries about AV (38.7%), altered their social media/selfie activity (23.7%), had an impact on real-life plans due to AV (22.9%), made efforts to hide AV (21.3%), felt picked-on/judged due to AV (15.0%), were concerned about their ability to reach future goals due to AV (13.8%), or had sleep impacted due to AV (18.2%). No significant change from baseline was observed for parent/caregiver's understanding of the child's AV concerns, from both patient and parent/caregiver perspectives.

**Conclusions:** Over 12 weeks of AV management with oral sarecycline, patients reported significant reductions in AV-related effects on emotional/social functioning and ADL as measured by the EPQ, a simple PRO with potential for use in clinical practice.

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# INTRODUCTION

cne vulgaris (AV) is a multifactorial inflammatory dermatosis pilosebaceous unit triggered by androgenof the driven hyperseborrhea, follicular hyperkeratinization, hypercolonization of *Cutibacterium acnes*, and inflammation.<sup>1-3</sup> It is the most common cutaneous disorder in the United States (US) and has an estimated global prevalence of 9.4%.4-8 Acne has significant morbidity associated with persistent scarring and psychosocial concerns that negatively affect quality of life (QoL), leading to low self-esteem and increased social and emotional anxiety.9-12 The psychosocial impact of AV is reported to be profound compared to other dermatologic diseases such as psoriasis and eczema.<sup>13</sup> Patient-reported outcome (PRO) measures have become increasingly emphasized in clinical practice for determination of disease effects and its impact on patients' and caregivers' health-related QoL (HRQoL).14 Studies focused on these issues have shown that AV can adversely affect a patient's mood, social/emotional functioning, activities of daily living (ADL), and general thoughts/worries about AV and their future goals.9,15,16 Patients and caregivers may also be concerned about side effects of treatment, particularly those associated with systemic therapies, such as broad-

spectrum antibiotics.<sup>17-23</sup> While several PROs have been developed for patients with acne, there remains a need for a targeted and concise list of questions for assessing the burden of AV.<sup>24</sup> This study incorporated a new PRO, the expert panel questionnaire (EPQ), in a 12-week study of sarecycline, a narrow-spectrum tetracycline antibiotic, in patients with AV.

# MATERIALS AND METHODS

#### Study Design

A 12-week single-arm prospective observational cohort study was carried out between March 2021 and May 2022 and enrolled 300 patients with AV who were administered sarecycline as part of usual care at one of 30 community US dermatology practices.

The study protocol was approved by the Advarra Institutional Review Board (SSU00149823 and SSU00150552). All participants provided written informed consent (assent, in the case of pediatric patients) prior to study initiation.

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Journal of Drugs in Dermatology	E. Grabe
February 2024 • Volume 23 • Issue 2 (Supplement 1)	

## E. Graber, H.E. Baldwin, R.G. Fried, et al

#### Participants

Patients were  $\geq$ 9 years of age with a confirmed clinical diagnosis of facial non-nodular AV, had an Investigator's Global Assessment (IGA) of score 3 (moderate) or 4 (severe), were deemed a potential candidate for sarecycline treatment per the clinician's judgment, and capable of adhering to study procedures. Adult primary caregivers for patients aged <12 years were included. Patients were excluded if they had any facial dermatologic or physical condition that could interfere with AV clinical evaluations; had a history of allergy to tetracycline-class antibiotics or antibiotic-associated or pseudomembranous colitis; had a known resistance to tetracyclines; were receiving concurrent treatment with oral retinoids or penicillin; or were pregnant, lactating, or planning a pregnancy during the study period.

#### Treatment

Clinicians prescribed oral sarecycline (60 mg, 100 mg, or 150 mg) to all eligible patients prior to their selection into the study, as part of usual care. Appropriate dosages were determined based on clinician judgment and as per US Food and Drug Administration prescribing guidelines.<sup>25</sup>

## FIGURE 1. Final version of the EPQ.

Assessments

The primary assessment and endpoint was the EPQ reported at baseline and week 12 by patients  $\geq$ 12 years and with the assistance of caregivers for those 9-11 years old.

Additional assessments included parental/caregiver concerns about the child's AV, understanding of the child's AV-related concerns, and the child's ability to accomplish future goals.

#### EPQ

The EPQ was developed for use in research studies to monitor and fully capture patient disease burden and treatment experiences, including the physical and psychosocial impact of AV. A 10-person consensus panel of dermatologists with expertise in the treatment of AV convened virtually and used a 3-step modified Delphi method to establish the questionnaire items; the panel included pediatric and skin of color specialists as well as 2 members with backgrounds in clinical psychology or psychiatry. Initially, a subgroup of panelists constructed items following a targeted literature review to identify over 50 PRO topics/items. This was reduced to 11 items considered most relevant for the assessment of AV burden.

1.	Over the past 7 days, ho	w often has your acne	made you feel angry (mad/s	ad)?	
	Never	Rarely	Some of the time	Most of the time	All of the time
2.	How worried are you about how long your acne will last and how bad it will get?				
	Not at all	Slightly	Somewhat	Moderately	Extremely
3.	How often do you think about your acne?				
	Never	Rarely	Some of the time	Most of the time	All of the time
4.	Over the past 7 days, ho	w worried have you be	een about your acne?		
	Not at all	Slightly	Somewhat	Moderately	Extremely
5.	How often do you change, edit, or filter your social media photo or selfie because of your acne?				
	Never	Rarely	Some of the time	Most of the time	All of the time
6.	How often does acne impact your "in real-life" plans (IRL) (like dating or social engagements, playing sports, swimming o hanging out)?				
	Never	Rarely	Some of the time	Most of the time	All of the time
7.	How often are you doing something to hide your acne (like mess with, squeeze/pop, or use makeup, concealer, hairstyle, clothes to cover up)?				
	Never	Rarely	Some of the time	Most of the time	All of the time
8.	How often do you feel picked on or judged because of your acne?				
	Never	Rarely	Some of the time	Most of the time	All of the time
9.	How concerned are you that your acne will affect your ability to reach your future goals (in school or work) and be the best you can be?				
	Not at all	Slightly	Somewhat	Moderately	Extremely
10.	Over the past 7 days, how often has worrying about or discomfort (itching/hurting) from acne affected your sleep?				
	Never	Rarely	Some of the time	Most of the time	All of the time

Please read and answer each of the following questions about how acne affect your emotional wellbeing, social interactions, and other daily activities. Before answering each question, look in the mirror and think about the acne on your face. Select one

Journal of Drugs in Dermatology February 2024 • Volume 23 • Issue 2 (Supplement 1)

The items were clustered into 3 domains for AV impact: emotional functioning (4-items), social functioning (3-items), and ADL (4-items). These items were complementary to the validated Acne Symptom and Impact Scale (ASIS) that the panel had chosen for use in the PROSES study.<sup>26,27</sup> The panelists proposed 6 additional questions for caregivers, including 3 questions (items 4, 9, and 10) from the main instrument, 1 question adapted from the ASIS questionnaire on current AV status, and 2 questions regarding concerns about antibiotics and antibiotic resistance. The total set of questions was reviewed and modified by the expert panel to provide a final questionnaire on which there was 100% agreement among experts for all items (Figure 1). In the main 11-item EPQ, items 1-9 and 11 were scored on a 5-point adjectival response scale (score: 0 [no burden/impact] - 4 [most burden/impact]); item-10 was scored on a 5-point scale (score: 0 [not at all] - 4 [very much]). The 6 additional questions were also scored on a 5-point scale (score 0-4). The EPQ was aligned with prior research evaluating issues impacting patients with AV.<sup>15,16</sup>The panel formulated the questions to be more relevant to the current social environment and addressed issues including bullying, embarrassment, social media manipulation, and perception of physical imperfection due to AV.

#### **Statistical Analysis**

All patients who received  $\geq 1$  dose of sarecycline and had  $\geq 1$  question answered at week 12 were included in the analyses. All continuous variables are presented as mean, standard deviation (SD), and number of patients; categorical variables are presented as counts and percentages. Discrete variables were analyzed using Chi-square tests. Statistical differences in continuous measures were assessed using paired t-tests. Items from the EPQ were analyzed individually. All statistical analyses were conducted using SAS statistical software and  $P \leq .05$  was considered statistically significant.

# RESULTS

#### **Patients and Caregivers**

A total of 253 patients received sarecycline throughout the study as part of usual care and had valid non-missing data at week 12. The baseline demographic characteristics for adult patients, pediatric patients, and caregivers are summarized in Table 1. The mean age was 26.6 years for adult patients (60.1%) and 14.8 years for pediatric patients (39.9%). The final cohort was predominantly female (66.4%) and White/Caucasian (68.4%). At baseline, most patients had moderate AV (86.6%) and the rest had severe AV (13.4%).

#### **Concerns about Antibiotic Use and Resistance**

The majority of adults were not at all/slightly concerned about antibiotic use for AV (79.6%) and antibiotic resistance (72.4%). Similarly, most caregivers were not at all or slightly concerned about antibiotic use for AV (68.3%) and antibiotic resistance (65.3%) (Figure 2).

#### **Disease Burden at Baseline**

Most of the patients with AV experienced high disease burden at baseline, with the emotional/social impact of AV more affected, as evidenced by the proportion of patients reporting "all/most/some of the time" on individual issues measured by EPQ items: 56.1% reported mood/anger issues, 79.4% worried about AV worsening, 84.2% were thinking about AV, 72.7% had some level of AV worries, 51.4% of patients often edited social media photo/selfie, 44.7% reported impact on real-life plans, 72.7% made efforts to hide AV, 26.9% reported being picked-on/

#### TABLE 1.

Demographic Characteristics of Patients and Caregivers			
Demographic Data	Adult Patients, ≥18 years old (N=152)	Pediatric Patients, <18 years old (N=101)	Caregivers (N=101)
Age, years			
Mean (SD)	26.6 (7.6)	14.8 (1.7)	45.9 (7.9)
Median (min, max)	24.0 (18.0, 50.0)	15.0 (10.0, 17.0)	48.0 (18.0, 65.0)
Sex			
Male, n (%)	34 (22.4)	51 (50.5)	19 (18.8)
Female, n (%)	118 (77.6)	50 (49.5)	82 (81.2)
Race			
White/Caucasian, n (%)	94 (61.8)	79 (78.2)	75 (74.3)
Black or African American, n (%)	18 (11.8)	7 (6.9)	7 (6.9)
American Indian or Alaskan, n (%)	1 (0.7)	1 (1.0)	1 (1.0)
Asian, n (%)	12 (7.9)	6 (5.9)	3 (3.0)
Native Hawaiian or other Pacific Islander, n (%)	1 (0.7)	2 (2.0)	0 (0.0)
Other, n (%)	28 (18.4)	11 (10.9)	12 (11.9)
Prefer not to answer, n (%)	4 (2.6)	4 (4.0)	4 (4.0)
Hispanic, Latino, or of Spanish origin			
Yes	55 (36.2)	31 (30.7)	31 (30.7)
No	97 (63.8)	70 (69.3)	70 (69.3)

max, maximum; min, minimum; N, population size; n, sample size; SD, standard deviation

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Journal of Drugs in Dermatology	E. Graber, H.E. Baldwin, R.G. Fried, et al
JARY 2024 • VOLUME 23 • ISSUE 2 (SUPPLEMENT 1)	

# FIGURE 2. Patient and caregiver concerns about antibiotics and antibiotic resistance.

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judged due to AV, 27.3% reported concerns about their ability to reach future goals, and 27.7% reported sleep impact. The majority reported adequate parental understanding of AV concerns (for patients <18 years old; Figure 3a and 3b).

# Disease Burden After 12 Weeks of Treatment With Sarecycline

Following 12 weeks of treatment, there was a significant increase ( $P \leq .0001$ ) in the proportions of patients responding that they never/

rarely: felt angry (31.6%); worried about AV worsening (28.9%); had thoughts about AV (20.9%); had a certain level of worries about AV (38.7%); altered their social media/selfie activity (23.7%); had an impact on real-life plans due to AV (22.9%); made efforts to hide AV (21.3%); felt picked-on/judged due to AV (15.0%); were concerned about their ability to reach future goals due to AV (13.8%); or had their sleep impacted due to AV (18.2%) (Figure 3a and 3b).

**FIGURE 3A**. EPQ responses for items 1, 3, 5, 6, 7, 8, and 11 vs baseline: \**P* ≤.0001; \**P* =.0005; \**P* =.0009; \**P* =.0042.



s	9
Journal of Drugs in Dermatology February 2024 • Volume 23 • Issue 2 (Supplement 1)	E. Graber, H.E. Baldwin, R.G. Fried, et al

## FIGURE 3B. Expert panel questionnaire responses for items 2, 4, 9, and 10 vs baseline: \*P <.0001; \*\*P <.0001; \*P =.0005; \*\*P =.0009; #P =.0042.



N=253 for all items, except for EPQ question 10, which corresponded to only caregivers of pediatric patients, with N=101.

#### TABLE 2.

Patient and Caregiver Comparison			
	Baseline	Week-12	
	(N=101)	(N=101)	
Parent/Caregiver: Do you feel that you understand your child's acne-related concerns right now?			
Not at all/A little, n (%)	7 (6.9)	7 (6.9)	
Somewhat, n (%)	18 (17.8)	22 (21.8)	
Quite a bit/Very much, n (%)	76 (75.3)	72 (71.3)	
Child: Do you feel that your parents understand your acne-related concerns?			
Not at all/A little, n (%)	16 (15.8)	17 (16.8)	
Somewhat, n (%)	26 (25.7)	21 (20.8)	
Quite a bit/Very much, n (%)	59 (68.4)	63 (62.4)	
Parent/Caregiver: Over the past 7 days, how concerned have you been about your child's acne?			
Not at all/A little, n (%)	15 (14.9)	63 (62.4)	
Somewhat, n (%)	29 (28.7)	17 (16.8)	
Quite a bit/Very much, n (%)	57 (56.4)	21 (20.8)	
Child: Over the past 7 days, how worried have you been about your acne?			
Not at all/A little, n (%)	36 (35.6)	68 (67.3)	
Somewhat, n (%)	35 (34.7)	25 (24.8)	
Quite a bit/Very much, n (%)	30 (29.7)	8 (7.9)	
Parent/Caregiver: How concerned are you about your child's ability to accomplish future goals and reach full potential due to acne?			
Not at all/A little, n (%)	47 (46.5)	68 (67.3)	
Somewhat, n (%)	28 (27.7)	16 (15.8)	
Quite a bit/Very much, n (%)	26 (25.8)	17 (16.5)	
Child: How concerned are you that your acne will affect your ability to reach your future goals (in school or work) and be the best you can be?			
Not at all/A little, n (%)	84 (83.2)	94 (93.1)	
Somewhat, n (%)	9 (8.9)	5 (4.9)	
Quite a bit/Very much, n (%)	8 (7.9)	2 (1.9)	
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N, population size; n, sample size

Journal of Drugs in Dermatology	E. Graber, H.E. Baldwin, R.G. Fried, et al
February 2024 • Volume 23 • Issue 2 (Supplement 1)	

There were corresponding significant (*P*<.005) decreases in the proportions of patients responding that they moderately/extremely or most/all of the time: felt angry (–13.0%); worried about AV worsening (–28.1%); had thoughts about AV (–28.1%); had a certain level of worries about AV (–34.8%); altered their social media/selfie activity (–20.2%); had an impact on real-life plans due to AV (–12.6%); made efforts to hide AV (–17.8%); felt picked-on/judged due to AV (–7.5%); were concerned about their ability to reach future goals due to AV (–9.1%); or had their sleep impacted due to AV (–6.3%) (Figure 3a and 3b).

Responses to additional questions revealed that almost twice as many parents/caregivers (56.4%) vs their children (29.7%) reported being quite a bit/very much concerned about (child's) AV at baseline. These values decreased to 20.8% and 7.9%, respectively, by week 12. Similarly, 25.8% of parents/caregivers and 7.9% of children reported being quite a bit/very much concerned about (child's) ability to reach future goals due to AV. These values decreased to 16.5% and 1.9%, respectively, by week 12. Most pediatric patients (62.4%) and their parents/caregivers (71.3%) reported that parents understood the child's AV-related concerns quite a bit/very much. There was little change in these values at week 12 (Table 2).

## DISCUSSION

AV and its sequelae have a profound influence on patients' physical, social, and psychological well-being, significantly reducing their social/emotional functioning.<sup>28</sup> This impaired QoL may be improved by successful treatment of AV.<sup>29</sup> An undesirable skin appearance may result in a body image that provokes anger, anxiety, humiliation, embarrassment, bullying, and stigmatization among peers. Identifying such concerns in patients with AV is pivotal to providing comprehensive care leading to clinical and overall psychosocial improvement.<sup>30</sup> It has been shown that AV can result in psychological disturbance,<sup>31</sup> interference with social/leisure activities, and social avoidance.<sup>30</sup> Careful assessment of the impact of AV on patient-reported social/emotional well-being, and overall disease burden, identify psychologically vulnerable patients, and support appropriate integrated treatment. It is also important for assessing the benefits of new AV therapies.<sup>32-34</sup>

Results from this real-world study employing the novel EPQ suggest that 12 weeks of oral antibiotic treatment significantly reduced the adverse effects of AV on emotional/social functioning and ADL. At the end of 12 weeks, high percentages of patients reported no/least impact of AV in each of the 3 domains assessed by the EPQ. Specifically, after 12-weeks of treatment, most patients responded that they never/rarely felt angry, altered their social media activity, felt an impact on their real-life plans due to AV, or had their sleep impacted due to AV. Treatment also positively affected patients' attitudes toward interactions via social media. At baseline, most patients chose to alter their appearance to hide their skin lesions, considering it to be personal imperfection and unattractive. At the conclusion of this study, patients seldom thought of

altering their social media activities, indicating less concern about their appearance, and suggesting increased self-confidence. By the end of the study, most patients never/rarely felt picked on/judged due to AV and were positive regarding their ability to reach future goals, suggesting improved self-esteem and social functioning. At the study's conclusion, a minority of patients reported that they most/all of the time made efforts to hide their AV, worried about AV worsening, or had concerns about their ability to reach future goals due to AV.

Reducing psychosocial stress should be considered a guiding principle in AV management. Employment of safe and effective therapeutic options, and monitoring of both clinical responses and PRO have the potential to significantly decrease psychosocial burden associated with AV.<sup>28</sup> If systemic antibiotics are used, proper stewardship supports the use of narrow-spectrum agents to minimize disruption of the normal microflora and limit development of resistance.<sup>22</sup>

Various validated scoring systems are being used to determine patients' QoL and the effectiveness of clinical interventions on patients' psychosocial well-being.<sup>32,35-37</sup> However, most do not focus on patients' social/emotional functioning and ADL, which remain under-explored; do not address facial AV or issues that matter most to young patients; and/or take a long time to administer.<sup>35,38</sup> The EPQ fills the unmet need in AV-related PRO measurement. The EPQ is sensitive to therapy, as it demonstrated improvements in patients receiving an efficacious acne treatment.<sup>25</sup> The questionnaire could be helpful in routine clinical practice to improve AV patient management and document health outcomes, including patients' emotional/social functioning.

This study had significant limitations. Results may be subject to biases such as recall bias, reporting bias, selection bias, and other biases commonly seen in real-world and open-label studies. Approaches such as standardized study inclusion/exclusion criteria, consecutive sampling, and diverse dermatology clinics/investigators from across the US with varied prior experience with sarecycline were employed to minimize biases.

## CONCLUSION

The novel EPQ appears to be a clinically relevant and responsive AVrelated PRO instrument that effectively measures the impact of the disease and its treatment. Appropriate AV treatment with sarecycline was associated with a reduction in psychosocial impairment and supports the conclusion that the EPQ is a promising tool for supplementing clinical judgment in AV management.

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JOURNAL OF DRUGS IN DERMATOLOGY E. Graber, H.E. Baldwin, R.G. Fried, et al FEBRUARY 2024 • VOLUME 23 • ISSUE 2 (SUPPLEMENT 1)

DISCLOSURES

Dr Graber reported receiving royalties from Wolters Kluwer Health and served as a consultant/advisor, research investigator, and/or speaker for Almirall SA, Cutera, Digital Diagnostics, Hovione, Keratin Biosciences, La Roche Posay, Lipidor AB, L'Oreal, Ortho Dermatologics, Sebacia, SolGel, Verrica, and WebMD. Dr Fried served as a research investigator and/or scientific advisor for AbbVie, BI, BMS, Dermavant, Dermira, EPI, Incyte, Janssen, LEO, Lilly, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Sun, and UCB. Dr Hebert reported receiving grants and/or honoraria from Almirall SA, Amryt, Arcutis, Dermavant, GSK, Incyte, Leo, Lilly, Novan, Pfizer, and Sun Pharma; and served as a member of Data and Safety Monitoring Board for GSK, Ortho Dermatologics, and Regeneron-Sanofi. Dr Del Rosso served as a research investigator, consultant/advisor, and/or speaker for AbbVie, Aclaris, Almirall, Amgen (Celgene), AnaptysBio, Arcutis, Athenex, Bausch (Ortho Dermatologics), Biofrontera, BioPharmX, Biorasi, Blue Creek, Botanix, Brickell, Bristol Myers Squibb, Cara Therapeutics, Cassiopea, Dermata, Dermavant, Encore, EPI Health, Ferndale, Galderma, Genentech, Incyte, Jem Health, LEO Pharma, La Roche-Posay, Lilly (Dermira), MC2, NOVAN, Pfizer, Ralexar, Regeneron, Sanofi-Genzyme, Sente, Solgel, Sonoma (Intraderm), Sun Pharma, UCB, Verrica, and VYNE (Foamix/MenIo). Dr Kircik served as an investigator, speaker, advisory board member, and/or consultant for Abbott Laboratories, Aclaris, Inc, Allergan, Inc, Almirall, Anacor Pharmaceuticals, Inc, Assos Pharma, Astellas Pharma US, Inc, Asubio Pharma Co, Ltd, Berlex Laboratories (Bayer Healthcare Pharmaceuticals), Biogen-Idec, Inc, Biolife, Biopelle, Boehringer Ingelheim, Breckinridge Pharma, Celgene Corporation, Centocor, Inc, Colbar, CollaGenex, Combinatrix, Connetics Corporation, Coria, Dermik Laboratories, Dermira, Inc, Dow Pharmaceutical Sciences, Inc, Dusa Pharmaceuticals, Inc, Eli Lilly & Co, Embil Pharmaceutical Co, Ltd, EOS, Ferndale Laboratories, Inc, Galderma Laboratories, LP, Genentech, Inc, GlaxoSmithKline, PLC, Health Point Ltd, Idera, Inc, Innocutis Medical, LLC, Innovail, Intendis, Inc, Johnson & Johnson, Laboratory Skin Care, Inc, Leo Pharmaceuticals, Inc, L'Oreal SA, 3M, Maruho Co, Ltd, Medical International Technologies, Medicis Pharmaceutical Corp, Merck & Co, Inc, Merz, Nano Bio Corporation, Novartis Pharmaceutical Corporation, Noven Pharmaceuticals, Inc, Nucryst Pharmaceuticals Corporation, Obagi Medical Products, Inc, Onset, Ortho Dermatologics, OrthoNeutrogena, PediaPharma, Inc, Promius Pharma, LLC. PharmaDerm, Pfizer, Inc, PuraCap, QLT, Inc, Quatrix, Quinnova, Serono (Merck-Serono International SA), SkinMedica, Inc, Stiefel Laboratories, Inc, Sun Pharmaceutical Industries, Ltd, Taro, TolerRx, Inc, Triax, UCB, Inc, Valeant Pharmaceuticals North America LLC, Warner-Chilcott, XenoPort, Inc, and ZAGE. Dr Stein Gold served as an investigator, advisor and/ or speaker for Almirall SA, Galderma, Ortho Derm, and Sun. Dr Harper reported receiving honoraria for serving as a consultant, speaker, and/ or investigator for Almirall, Cassiopeia, Cutera, EPI, Galderma, Journey, L'oreal, Ortho, Sol Gel, Sun, and Vyne and received honoraria for holding stocks in Cutera. Dr Alexis reported receiving grants and/or royalties from Abbvie, Almirall SA, Amgen, Arcutis, Bristol-Myers-Squibb, Cara, Castle, Dermavant, Galderma, Leo, Novartis, Springer, Wiley-Blackwell, Wolters Kluwer Health, Valeant (Bausch Health), and Vyne; and served

as a consultant/advisor and/or speaker for Abbvie, Allergan, Almirall SA, Amgen, Arcutis, Bausch health, Beiersdorf, BMS, Cara, Castle, Cutera, Dermavant, Eli Lilly, EPI, Galderma, Incyte, Janssen, Leo, L'Oreal, Ortho, Pfizer, Sanofi-Genzyme, Sanofi-Regeneron, Swiss American, Regeneron, UCB, VisualDx, and Vyne. Dr Narayanan reported receiving consulting honoraria or research funding from Almirall, Biogen, Johnson and Johnson, Sarepta Therapeutics, SeaGen, and Takeda. Dr Koscielny and Dr Kasujee are employees of Almirall, SA. No other conflicts were reported.

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