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Title: Analysis of conflicts of interest in pharmaceutical payments made to FDA physician advisers after dermatologic drug approval

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Introduction

Academic physicians have regularly served as voting members of advisory committees for the Food and Drug Administration¹⁻³. These committee members serve as external experts to the FDA in determining whether a new medical therapy is fit for the United States (US) market^{2, 3}. Considering that financial conflicts of interest (FCOIs) have been shown to impact member voting habits, physician financial ties have been a topic of ongoing discussion²⁻⁵. A recent study found that many former FDA advisors receive large sums of money from pharmaceutical companies once their advisory role is complete³. Some fear these relationships may incentivize future committee members to expect after-the-fact rewards for favorable voting habits³. While the FDA has guidelines to minimize FCOI, it does not make stipulations about post-advisory role financial relationships³.

Investigations using Open Payment data have analyzed post-hoc advisory role payments to physician advisors in the approval of psychopharmacologic, rheumatologic, cardiac, and renal drugs.² These analyses have not been reported for dermatologic drug advisors. The purpose of this study is to review Open Payment data for industry payments made to former dermatologic drug committee members.

Method

Payments made to U.S. physicians who advised FDA committees during the approval of eight dermatologic therapies were analyzed using the publicly available Centers for Medicare and Medicaid Services Open Payment database. Drugs were chosen from recently approved dermatology medications from CenterWatch.com and

included those used frequently and infrequently by dermatologists (brodalumab, dalbavancin, deoxycholic acid, dupilumab, peginterferon alfa-2b, secukinumab, tedizolid phosphate, and ustekinumab).³ Data was collected from 2013 to 2017. This range was selected because there is no data available prior to 2013, and 2017 correlated with the most recent data available.⁴ Payments classified as general payments were recorded and included consulting fees, speaking fees, educational expenses, food and beverage expenses, and travel and lodging expenses.

Results

Of the 61 physician advisers, 33 (54%) received at least one industry payment following dermatologic drug approval. Of the 33 receiving one payment, nine (27%) accepted more than \$1,000, six (18%) accepted more than \$10,000, five (15%) accepted more than \$50,000, and three (9%) accepted more than \$100,000. The 33 physician advisers received a mean of \$47,860.62 (SD $\pm$ 85,938). The standard deviation was greater than the mean due to the non-normal distribution of the data. For the drugs examined, payments from competing pharmaceutical companies outnumbered payments from the drug manufacturer (**Table 1**).

Discussion

Our research concludes former FDA committee advisers for dermatologic drugs received payments from industry on a frequent basis. Furthermore, a significant proportion (24%) of those who accepted payments received funds in excess of \$50,000. Critics of such industry-physician relationships argue these payments could incentivize FDA advisers to alter their voting habits³. Others conclude post-hoc industry payments should not be discouraged as quality researchers are likely to be pursued by industry,

and these mergers can lead to scientific advancements that benefit society^{2, 3}.

Regardless of the ongoing debate, awareness of physician-industry financial ties is worthy of continued discussion. Future evaluations may help assess trends in post-hoc advisory payments.

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Table 1. Payments made to voting members of FDA drug committees by pharmaceutical companies. Table excludes payments for research purposes.

Brodalumab	
Competitor Payments	\$85,249.89
Manufacturer (Valeant Pharmaceuticals) Payments	\$0.00
Total Payments	\$85,249.89
Dalbavancin	
Competitor Payments	\$210,478.76
Manufacturer (Allergan, Inc.) Payments	\$2,262.77
Total Payments	\$212,741.53
Deoxycholic acid	
Competitor Payments	\$218,910.73
Manufacturer (Kythera Biopharma) Payments	\$0.00
Total Payments	\$218,910.73
Dupilumab	
Competitor Payments	\$44,226.33
Manufacturer (Sanofi & Regeneron) Payments	\$29,587.09
Total Payments	\$73,813.42
Peginterferon alpha	
Competitor Payments	\$792,090.19
Manufacturer (Merck) Payments	\$71,907.98
Total Payments	\$863,998.17
Secukinumab	
Competitor Payments	\$101,392.93
Manufacturer (Novartis) Payments	\$0.00
Total Payments	\$101,392.93
Tedizolid phosphate	
Competitor Payments	\$212,762.97

Manufacturer (Cubist Pharmaceuticals) Payments	\$0.00
Total Payments	\$212,762.97
Ustekinumab	
Competitor Payments	\$120,788.88
Manufacturer (Janssen Biotech) Payments	\$218.76
Total Payments	\$121,007.64