Title

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Authors

Carr, Noah J
Haslam, Alyson
Prasad, Vinay

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Financial conflicts among physician speakers at the April 12, 2024 Oncology Drug Advisory Meeting: Who decided that MRD can be a novel regulatory endpoint in myeloma?☆

Noah J. Carr [a], Alyson Haslam [b], Vinay Prasad [b,*]

[a] University of Arizona College of Medicine - Phoenix, Phoenix, AZ, USA
[b] Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, CA, USA

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ABSTRACT

Background: In April 2024, the Oncology Drug Advisory Committee (ODAC) voted to approve minimal residual disease (MRD) as a new regulatory endpoint for multiple myeloma (MM) despite its poor trial-level surrogacy. This is expected to result in faster MM drug approvals, a potential boon for the pharmaceutical companies that make them. This study investigates the prevalence of financial conflicts of interest (FCOIs) with these companies among United States (US)-based physician speakers at the meeting.

Methods: Public data regarding the past 3 years of pharmaceutical company payments to US-based physician speakers at the ODAC meeting discussing MRD (available at https://openpaymentsdata.cms.gov/) were collected. For each general payment (GP), we recorded the amount, company payor, reason for payment, and associated products. Descriptive analyses were performed on payments from companies who manufacture MM therapeutics (MM payments).

Results: 12 of the 20 physician speakers (60 %) eligible to have FCOIs recorded on the OpenPayments database received MM payments from 2021 to 2023, totaling more than $792,200. A majority of both voting and non-voting members had MM payments (median $11,800 and $764), most of which were consulting fees. Speakers earned more than 3.7 times as much from GPs associated with MM-related products compared to those associated with non-MM-related products.

Conclusion: Most US-based physician speakers at the April 2024 ODAC meeting had FCOIs from MM companies, including those with voting power.

Policy summary: Our findings highlight the need for greater policing of FCOIs among US-based physicians involved in cancer drug regulatory policy.

1. Introduction

The United States (US) Food and Drug Administration (FDA) convenes drug advisory committees to review the safety and efficacy of new drugs or medical devices. These meetings solicit diverse perspectives from FDA officials, consumer and patient representatives, the pharmaceutical industry, academia, and members of the general public. There are now more than 50 FDA advisory committees, each focusing on a specific patient population or area of medicine [1]. While the FDA is not obliged to follow a committee's recommendations, their decisions usually align [2,3].

On April 12, 2024, the Oncology Drug Advisory Committee (ODAC) met with a different goal. Instead of discussing a drug or product, the committee was asked whether there was sufficient evidence to use a new regulatory endpoint, MRD, to approve drugs for MM. MRD assays use flow cytometry or sequencing to detect whether there are microscopic cancer cells in patients' bone marrow after completing therapy [4]. Although MRD negativity is prognostic for overall survival (OS) at the individual patient level [4], there have been no analyses showing strong trial-level surrogacy for clinical endpoints. In other words, therapies that improve MRD negativity have not been shown to reliably improve outcomes that intrinsically matter to patients, such as OS or

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* Correspondence to: Department of Epidemiology and Biostatistics, UCSF Mission Bay Campus, Mission Hall: Global Health & Clinical Sciences Building, 550 16th St, 2nd Fl, San Francisco, CA 94158, USA.
E-mail address: Vinayak.Prasad@ucsf.edu (V. Prasad).

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health-related quality of life. This was recapitulated by three meta-analyses reviewed at the April 2024 ODAC meeting. Regarding these data, an FDA official stated that "there was a lack of strong trial-level association, and therefore, MRD was not established as a validated surrogate endpoint" [5]. Despite these caveats, the committee approved MRD as a new regulatory endpoint in a unanimous vote. This has significant implications for ongoing trials that use MRD negativity as their primary endpoint, such as the phase 3 BENEFIT [6] and GMMG-HD7 trials [7].

Financial conflicts of interest (FCOIs) with pharmaceutical companies pervade many areas of medicine [8], including oncology [9–12]. These FCOIs increase physicians' likelihood of endorsing [13] and prescribing [14] those companies' medications. Since the most widely advertised drugs are often of relatively high price and may not always provide meaningful clinical benefit [15], physician FCOIs may plausibly affect patients' standard of care. This is particularly true in oncology, in which higher drug prices do not reflect better efficacy [16] and a large share of industry payments are concentrated among physicians with leadership roles [11].

Payments from pharmaceutical companies to US-based physicians are recorded in the Center for Medicare & Medicaid Services's Open-Payments database (https://openpaymentsdata.cms.gov/). Using publicly available data, we sought to characterize the prevalence of FCOIs among speakers at the April 12, 2024 ODAC meeting.

2. Materials and methods

We collected the names of all speakers at the April 12, 2024 ODAC meeting using the FDA's public transcript. For each person, we noted their role in the meeting (voting member or speaker), their degree (MD, PhD, or other), and affiliation (FDA, industry, or other). Names of US-based physicians were identified and searched within the https://openpaymentsdata.cms.gov/ database on August 30, 2024. If a physician had received one or more general payments (GPs) during 2021–2023, we collected the following information for each: total amount, company payor, nature of payment, and associated drugs or products. US-based physicians without information available on the OpenPayments database were assumed to have $0 in GP, including one physician who was excluded from the analysis because they were a full-time pharmaceutical company employee and thus did not have their payments recorded within the database. For GPs with more than one associated drug/product, we divided the payment amount equally between the drugs/products. If associated drugs/products were approved prior to 2023, we collected the 2023 revenue from publicly available financial reports when available.

We determined whether company payors were involved in the MM field by whether they, their parent company, or a subsidiary manufactures or receives royalties from a brand-name MM drug or MRD testing platform. This included Novartis, which had their only brand-name MM drug (panobinostat) withdrawn from the market in March of 2022. Drugs were classified as "brand-name" if they were made by only one company or if they were the original version of a now-generic medication. For instance, Revlimid was the original brand-name for lenalidomide, for which generics became available in 2022. Similarly, we classified the drugs and products associated with GPs based on whether they were FDA-approved for the treatment or diagnosis of MM.

We classified payments based on the labels provided by the Open-Payments database. The same descriptors (consulting, food and beverage, etc.) were used except for the two listed below, which were collectively categorized as "other:"

- "Compensation for serving as faculty or as a speaker for a medical education program."
- "Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program."

Our analyses were descriptive, and we calculated payment medians for voting and non-voting speakers, respectively. The statistical difference between these medians was calculated using the Wilcoxon-Rank Sum test. Spearman correlation was used to assess possible association between the total 2021–2023 GPs received in association with a product and the revenue it generated during the 2023 financial year. Both figure creation and statistical analysis were accomplished using Google Sheets and RStudio (version 2024.04.2 +764).

In the manuscript, dollar amounts greater than $1000 were rounded to the nearest $100 while those less than $1000 were rounded to the nearest $1. All percentages were rounded to the nearest hundredth of one percent.

We did not submit this study for institutional review board approval because it involved publicly available data and did not involve patient data.

3. Results

Thirty-five speakers at the meeting were identified: 8 FDA officials (5 physicians, 2 statisticians, and 1 pharmacist), 7 industry representatives (4 physicians [including 1 full-time pharmaceutical company employee], 2 statisticians, and 1 basic science researcher), and 20 individuals of various other affiliations (12 physicians, 4 MM patients [one of whom was a nonprofit executive], 2 statisticians, 1 other nonprofit executive, and 1 consumer representative). Among the 20 people in the latter group, there were 12 voting members: 8 physicians, 2 statisticians, 1 consumer representative, and 1 patient representative.

20 of the 21 physicians speakers were eligible to have payments recorded within the OpenPayments database (one full-time pharmaceutical company employee was not). Of those, 12 (60 %) received at least one MM payment during 2021–2023 (Fig. 1). MM payments comprised 515/625 (82.4 %) of all GPs (Supplementary Tables 1 - 2; Supplementary Figure 1) and totaled $792,200. Total MM payments per speaker ranged from $0 to $230,146, with a median of $8000. Individual MM payment size, by contrast, ranged from $2 to $22,900, with a median of $700.

Six of the 8 (75 %) physician speakers who voted on whether to approve MRD as a regulatory endpoint received MM payments during 2021–2023, with a median of $11,800 (range $0 - $34,500). The non-voting members, by contrast, received a median of $764 (range $0 - $230,100) over the same time period. Despite the greater range in the latter group, there was no statistical difference between the two (p-value = 1, Fig. 2).

Payments were grouped into 7 broad categories: consulting, education, travel and lodging, education, honoraria, grants, and other. As shown in Fig. 3, $555,600 (68.97 %) of MM payments were made for consulting. This was followed, in descending frequency, by other ($164,700; 20.45 %), travel and lodging ($32,075.51; 3.98 %), honoraria ($29,555; 3.67 %), education ($12,500; 1.55 %), food and beverage ($10,700; 1.33 %), and grants ($500; 0.06 %).

CMS allows up to 5 drugs or products to be associated with a single GP. Of note, 415/625 (66.4 %) of GPs received by ODAC speakers had such an association. Of the 58 drugs and products associated with GPs, 16 (27.59 %) were related to diagnosis or treatment of MM (Supplementary Table 3). The sum of payments associated with MM-related products ($428,100) was 3.7 times greater than that of non-MM-related products ($115,700). The nature of these payments was similar to the trend described previously, with most of the funds dedicated to consulting and the least to grants (Fig. 4). There was no relationship between the sum of payments associated with a particular product and its profitability during the 2023 financial year (Spearman correlation coefficient = −0.08, Supplementary Figure 2).

4. Discussion

By hosting voices from academia, industry, and patient advocacy

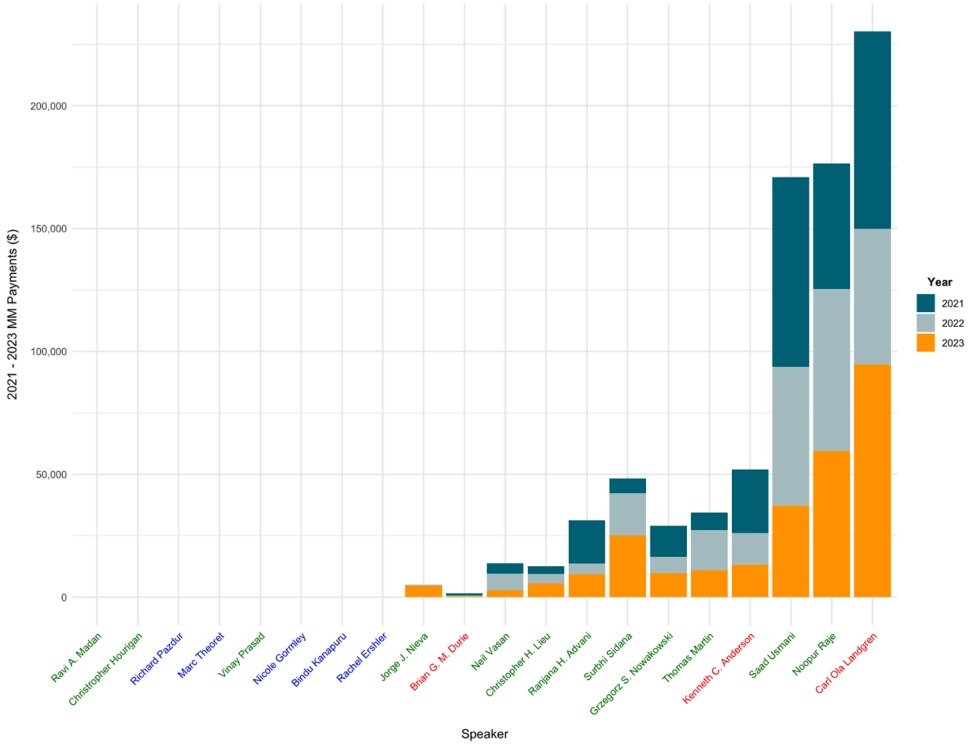

Fig. 1. Total 2021–2023 MM Payments to April 2024 ODAC Speakers. Speaker affiliations classified as FDA (blue), Industry (red), and Other (green).

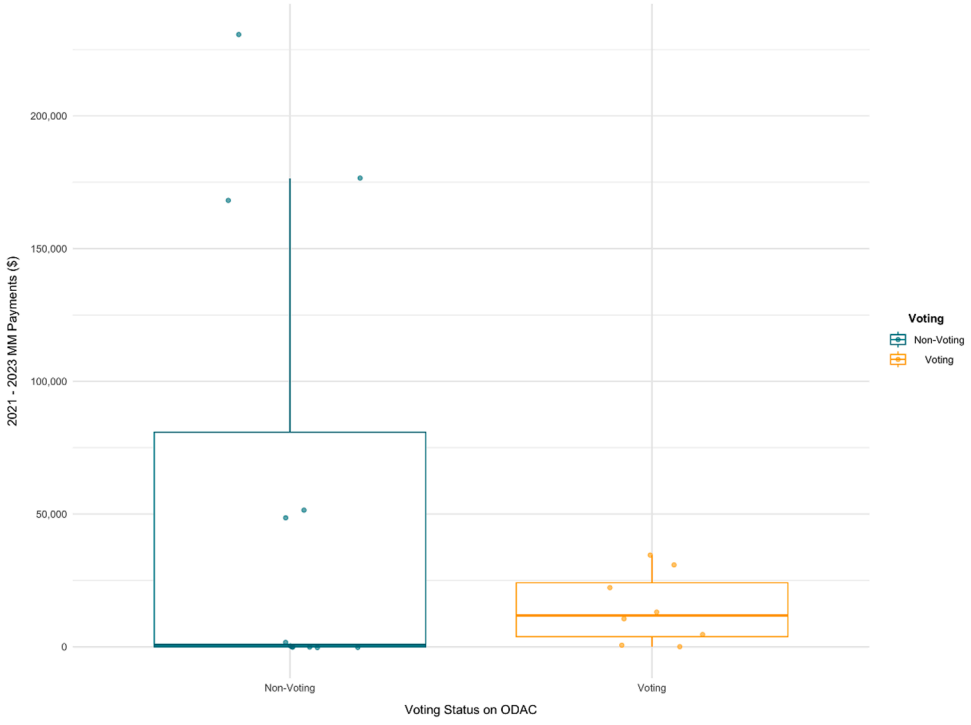

Fig. 2. Total 2021–2023 MM Payments to Voting vs Non-Voting April 2024 ODAC Speakers. Distributions are not statistically different using the Wilcoxon rank-sum test (p-value = 1).

organizations, ODAC meetings attempt to provide a balanced discussion of cancer regulatory policy. Ideally, there should not be undue influence from parties expected to benefit from its decisions. This is of interest to the public, who broadly support FDA transparency measures [17]. As stated by industry representatives in the April 2024 ODAC meeting, the use of MRD as a regulatory endpoint would likely result in MM therapeutics being approved "more quickly than today" [18]. Additionally, MRD is inherently more permissive, as some products may be approved that do not later improve progression-free survival. It is therefore important to understand the financial relationships between the companies marketing MM drugs, meeting presenters, and the ODAC members who oversee regulatory decisions.

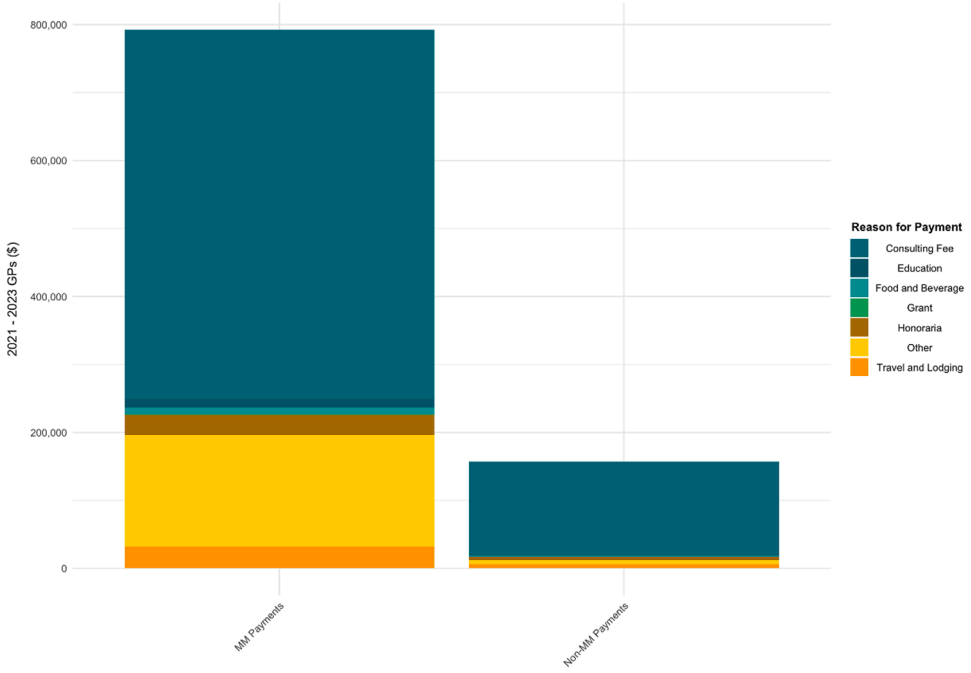

Fig. 3. Characterization of 2021–2023 Payments from MM vs Non-MM Companies.

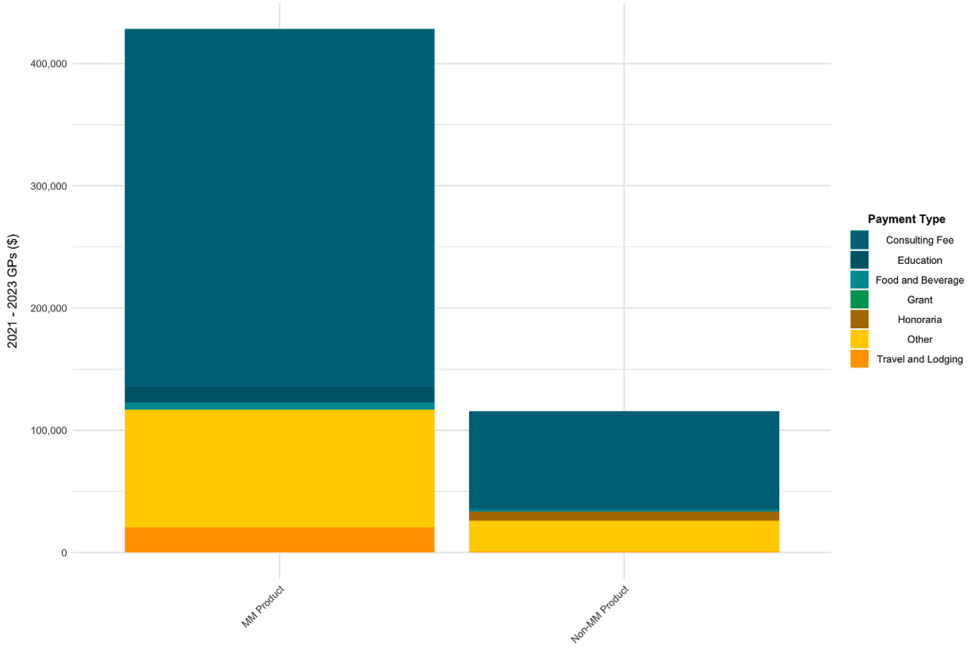

Fig. 4. Characterization of 2021–2023 GPs Associated with MM vs Non-MM Products.

Our study revealed that 60 % of the physician speakers at the April 2024 ODAC meeting received payments from MM companies during 2021–2023. Concerningly, this finding extended to the voting members of the committee, with six of eight receiving such payments (median $11,800). While one might expect voting members to be less conflicted, their median MM payment ($11,800) was numerically higher than that of their non-voting counterparts ($764). Furthermore, about two thirds of GPs were associated with various drugs, including MM therapeutics. Payments associated with MM-related products earned speakers more than 3.7 times as much as those that were associated with non-MM-related drugs despite the former being less common. Of note, this included more than $17,800 associated with the promotion of an MRD testing platform.

Our findings raise an important question: do FCOIs within drug advisory committee meetings affect their final recommendations? Prior studies by Khan et al. [19] and Lurie et al. [20] both failed to detect an association. Similarly, Xu and colleagues [21] found no relationship between speakers' *past* financial relationships (so-called section 502 conflicts) and voting patterns. However, given the fixed number of prior decisions, studies attempting to assess voting bias may be underpowered to detect meaningful, but modest differences. At the same time, our analysis raises concern at the sheer number of conflicted panelists and limited number of non-conflicted speakers. The preponderance of evidence [9–11] suggests that physicians, like anyone else, can be

susceptible to bias.

While the existence of databases like OpenPayments is a step forward, there are persistent issues with FCOI transparency and disclosure [22,23]. Prior editorialists have [24,25] outlined proposals to minimize the impact of financial conflicts in oncology. While ODAC recommendations are non-binding, the FDA follows them in a majority of cases [2,3], underscoring their importance in shaping cancer drug policy. Our findings suggest that more can be done to limit FCOI in ODAC meetings and, thus, in the approval process of new regulatory endpoints such as MRD.

4.1. Limitations

One limitation of our study was restricting analysis to speakers at the April 2024 ODAC meeting. Broadening our scope to include other MM-related meetings may have yielded a more complete picture of how FCOI affects the field. However, we chose to focus on the April 2024 meeting because it, unlike most meetings, discussed a novel regulatory endpoint rather than a drug approval. Second, our assessment of FCOI was limited by the constraints of the OpenPayments database, which only tracks payments to US-based physicians, and may not include payments to those who are full-time pharmaceutical employees. Our analysis was therefore unable to assess whether FCOI were present among other types of speakers, potentially resulting in an underestimate.

5. Conclusions

A majority of voting and non-voting US-based physician speakers at the April 2024 ODAC meeting, where regulatory endpoints for MM drugs were discussed, had significant FCOIs with MM companies. Efforts to remove FCOIs from ODAC and similar meetings may increase patient trust and improve the regulatory processes that shape patient care.

6. Disclosure

V.P. receives research funding from Arnold Ventures through a grant made to UCSF, and royalties for books and writing from Johns Hopkins Press, MedPage, and the Free Press. He declares consultancy roles with UnitedHealthcare and OptumRX; He hosts the podcasts, Plenary Session, VPZD, Sensible Medicine, writes the newsletters, Sensible Medicine, the Drug Development Letter and VP's Observations and Thoughts, and runs the YouTube channel Vinay Prasad MD MPH, which collectively earn revenue on the platforms: Patreon, YouTube and Substack. None of the other authors have any potential conflicts of interest to declare.

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CRediT authorship contribution statement

Noah James Carr: Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft, Writing – review & editing. **Alyson Haslam:** Methodology, Supervision, Visualization, Writing – review & editing. **Vinay Prasad:** Conceptualization, Supervision, Writing – review & editing.

Declaration of Competing Interest

V.P. receives research funding from Arnold Ventures through a grant made to UCSF, and royalties for books and writing from Johns Hopkins Press, MedPage, and the Free Press. He declares consultancy roles with UnitedHealthcare and OptumRX; He hosts the podcasts, Plenary Session, VPZD, Sensible Medicine, writes the newsletters, Sensible Medicine, the Drug Development Letter and VP's Observations and Thoughts, and runs the YouTube channel Vinay Prasad MD MPH, which collectively earn revenue on the platforms: Patreon, YouTube and Substack. None of the other authors have any interests to declare.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jcpo.2024.100529.

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