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ORIGINAL ARTICLE

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Financial conflicts of interest among presenters, panellists and moderators at haematology and oncology FDA workshops

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Abstract

Objective: To assess the characteristics and financial conflicts of interest of presenters, panellists and moderators at haematology and oncology workshops held jointly with or hosted by the US FDA.

Setting: We included information on all publicly available haematology or oncology FDA workshop agendas held between 1 January 2018 and 31 December 2022.

Exposure: General and research payments reported on Open Payments, industry funding to patient advocacy organizations reported on their webpages or 990 tax forms and employment in both pharmaceutical and regulatory settings.

Results: Among physicians eligible for payments, 78% received at least one payment from the industry between 2017 and 2021. The mean general payment amount was $82,170 for all years ($16,434 per year) and the median was $14,906 for all years ($2981 per year). Sixty-nine per cent of patient advocacy speakers were representing organizations that received financial support from the pharmaceutical industry. Among those representing regulatory agencies or pharmaceutical companies, 16% had worked in both settings during their careers.

Conclusions and Relevance: Our findings in this cross-sectional study show a majority of US-based physician presenters at haematology and oncology workshops held jointly with members of the US FDA have some financial conflict of interest with the pharmaceutical industry. These findings support the need for clear disclosures and suggest that a more balanced selection of presenters with fewer conflicts may help to limit bias in discussions between multiple stakeholders.

KEYWORDS

conflict of interest, drug approval, FDA workshop, financial conflict of interest, hematology, oncology

1 | INTRODUCTION

The US Food and Drug Administration (FDA) hosts and presents at workshops each year, providing opportunities for regulators, patient advocates, academics and industry representatives to discuss strategies for advancing new treatments of hematologic and oncologic conditions. Presenters from all groups provide important perspectives

and insights into the current state and future directions of clinical treatment, regulatory strategy and clinical trial methodologies within their respective areas of expertise. Collaboration between these groups, including between physicians and industry, is important for translational research and the improvement of patient care. However, compensating physicians for their efforts in these collaborations should be weighed carefully against the cost of potentially introducing bias in prescribing practices, discussions with patients and discussions with regulators.

Prior research has shown that financial conflicts of interest (FCOI) in the form of industry payments can influence physician prescribing practices,[1] professional networking behaviour,[2] and social media behaviour.[3] Prior work has also found high rates of financial conflicts among public speakers at FDA advisory committee meetings[4] and experts testifying on behalf of drug companies.[5] Yet, no study has focused on workshops—which serve a distinct purpose from advisory committee meetings, as these are not tied to specific drug products, but broader regulatory frameworks in a disease condition.

Given the critical role presenters play in providing expert input[6] in discussions with regulators and other stakeholders, we sought to better understand the characteristics of those individuals who present at workshops affiliated with the FDA. To do so, we identified speakers, moderators and presenters at workshops from publicly available agendas and evaluated the professional characteristics and industry payments made to those individuals.

Key points

- *Question*: What are the characteristics of presenters, panellists and moderators at haematology and oncology workshops held jointly with the US FDA and do they have financial conflicts of interest with the pharmaceutical industry.
- *Findings*: In this cross-sectional study, we found that the majority (78%) of US-based physician presenters, panellists and moderators received at least one payment from the industry in the last 5 years. The mean general payments over 5 years were $82,170 ($16,434 per year) and the median was $14,906 ($2981 per year).
- *Meaning*: Given the important role presenters play in guiding discussions with many stakeholders at US FDA workshops, efforts should be made to create balanced panels of presenters with limited conflicts of interest.

2 | METHODS

We sought to study the speakers, moderators and presenters at US FDA workshops and evaluate potential conflicts of interest with the industry, potential conflicts with the underlying patient organizations they represented and potential conflicts presented by future job opportunities.

2.1 | Study population

We identified haematology and oncology-related workshops hosted by or held jointly with representatives of the FDA between 1 January 2018 and 31 December 2022, using the FDA website[7] and Google. Our Google search terms included "FDA workshops" AND "oncology" OR "haematology". We excluded workshops unrelated to therapeutics or clinical trials and those for which an agenda was unavailable. The names and affiliations of the presenters were extracted from each workshop agenda and recorded. We classified affiliations as FDA, industry, academic, patient advocacy or other. In addition, we noted whether the presenter was from the United States, their degree, institution and the number of times they presented at different workshops.

2.2 | Financial conflicts of individuals

For each US-based physician who presented, we searched the Center for Medicare & Medicaid Services (CMMS) Open Payments database[8] to obtain payment data for the years 2017–2021. The CMMS Open Payments database is a publicly available resource that provides information about payments US physicians receive from drug and medical device companies. We collected general payments data, described by the Center for Medicare & Medicaid Services as "payments that are not associated with a research study," as well as research payments for each physician in our dataset. We excluded physicians outside of the US because the Open Payments database does not include information about them.

2.3 | Financial conflicts of patient advocacy organizations

In addition to assessing FCOI among physicians, we were interested in the potential FCOI between patient advocacy groups represented at workshops and pharmaceutical companies. To examine this conflict, we collected reported funding information from the patient advocacy groups' webpages or their 990 tax forms if they were

US-based non-profit organizations and noted whether any funding came from pharmaceutical companies.

2.4 | Financial conflicts presented by revolving door politics

The final source of potential conflict we sought to examine was the "revolving door" between regulatory agencies and the pharmaceutical industry, whereby regulators seek employment in the pharmaceutical industry after their service. To better understand the relationship and potential conflict between presenters of these two groups, we collected information on whether representatives of the regulatory agencies participating in the workshops went on to be employed by a pharmaceutical company; or whether the regulatory agencies had previously employed representatives presenting on behalf of the pharmaceutical industry.

We searched Google, PubMed and LinkedIn, using each participant's first and last name and the organization they were affiliated with at the time of the workshop to collect publicly available information on current and former employment. We noted when participants had been employed by both the pharmaceutical industry and a regulatory agency during their careers and their length of employment at the regulatory agency.

2.5 | Disclosures

Lastly, we sought to determine whether presenters disclosed their conflicts of interest during the workshop and characterize those conflicts. We searched the workshop hosts' webpages for presentation materials, video recordings or transcripts. We recorded when presenters had a disclosure slide or mentioned disclosures when presenting and what type of disclosure was listed, if any. Conflicts of interest were categorized as 'no conflicts', 'research funding', 'consulting', 'founder', 'honoraria', 'advisory board' or 'spouse'. For presenters who were also US physicians, we noted whether their disclosure statement was consistent with the industry payment information collected using the CMMS Open Payments database, using payment data reported prior to the date of the workshop at which they were presenting.

2.6 | Statistical analysis

We calculated descriptive statistics for presenters. For payments, we calculated the 5-year mean and median payments as well as the 1-year mean and median payments for each person eligible for Open Payments. We used Microsoft Excel (version 16.22), Stata (version 17.0) and R statistical software (version 4.2.2; Build 8160) for data analysis and visualization. Institutional Review Board approval was not required, as all data were publicly available.

3 | RESULTS

Our search identified 70 workshops, of which 37 met our inclusion criteria (Table S1). Reasons for exclusion included: Twenty-nine were unrelated to therapeutics or clinical trials, focusing instead on important social issues and education and four were excluded because there was no agenda available.

3.1 | Characteristics of presenters, panellists and moderators

Among the 37 workshops that met our inclusion criteria, there were 1187 total presenters, moderators or panellists. Thirty-three per cent ($n = 387$) of participants were affiliated with academic institutions, 14% ($n = 173$) were representing pharmaceutical companies, 28% ($n = 329$) were representing a regulatory agency, 10% ($n = 118$) were representing patient advocacy organizations and 15% ($n = 180$) were representing another organization, including non-academic public research institutions, consulting companies and data analytics companies (Table 1).

Representatives of regulatory agencies were mainly from the US FDA (92%, $n = 304$). A minority were from European regulatory agencies ($n = 22$), Canada ($n = 2$) and Japan ($n = 1$). Physicians made up 58% ($n = 696$) of total participants; 50% ($n = 599$) were based in the US, and 8% ($n = 97$) were based outside of the US (Table 1).

3.2 | Financial conflicts of individuals

To assess payments, we removed the names of individuals who presented at more than one workshop and identified 273 unique US-based physicians eligible for payments between 2017 and 2021. Of those, 78% ($n = 213$) had received at least one payment in the last 5 years. Between 2017 and 2021, US physicians in the study received an average of $82,170 and a median of $14,906 (IQR, $37–$88,106) in general payments. The average general payment per year was $16,434 and the median per year was $2981 (IQR, $7.4–$17,621) (Table 2). We found that 66% of physicians received mean payments of $10,000 or less per

TABLE 1 Characteristics of presenters, panellists and moderators listed on workshop agendas (n=1187).

	Academic	Pharmaceutical industry	Regulatory agency	Patient advocacy	Other	Total No. (%)
Physicians (US)	245	70	199	2	83	599 (50%)
Physicians (non-US)	53	7	15	6	16	97 (8%)
PhD	68	61	84	28	48	289 (24%)
MS	4	19	11	33	15	82 (7%)
Other clinical[a]	8	9	14	3	7	41 (4%)
Other non-clinical[b]	9	7	6	46	11	79 (7%)
Total no. (%)	387 (33%)	173 (14%)	329 (28%)	118 (10%)	180 (15%)	

[a]Includes nursing and pharmacy degrees.

[b]Includes individuals with business, law or no degree listed.

TABLE 2 Distribution of payments made to US-based physician presenters, panellists and moderators.

	General payments per year ($)	General payments 2017–2021 ($)
Mean	16,434	82,170
Median (IQR)	2981 (7.4–17,621)	14,906 (37–88,106)
	Distribution of general payments per year	**Distribution of general payments 2017–2021**
Received $0, No. (%)	64 (23.4)	64 (23.4)
Received <$10,000,[a] No. (%)	118 (43.2)	57 (20.9)
Received >$10,000,[b] No. (%)	84 (30.8)	89 (32.6)
Received >$100,000, No. (%)	7 (2.6)	63 (23.1)
	Research payments per year ($)	**Research payments 2017–2021 ($)**
Mean	2599	12,997
Median (IQR)	0 (0–1029)	0 (0–5260)
	Distribution of research payments per year	**Distribution of research payments 2017–2021**
Received $0, No. (%)	163 (59.7)	163 (59.7)
Received <$10,000,[a] No. (%)	93 (34.1)	60 (21.9)
Received >$10,000,[b] No. (%)	17 (6.2)	40 (14.7)
Received >$100,000, No. (%)	0 (0)	10 (3.7)

[a]Does not include $0 value.

[b]Does not include values >$100,000.

year, 23% received between $10,000 and $50,000 per year, 8% received between $50,000 and $100,000 per year and the top 3% received above $100,000 per year (Figure 1).

3.3 | Financial conflicts of patient advocacy organizations

Patient advocates representing 52 organizations made up 10% (n=118) of the total participants. Sixty-nine per cent (n=82) spoke on behalf of organizations that received financial support from the pharmaceutical industry (Figure 2). Among the 52 organizations represented, 56% (n=29) received funding from the industry based on the description of supporters on their webpage or their tax filings.

3.4 | Financial conflicts presented by revolving door politics

Among all presenters representing a regulatory agency, we found that 18% (n=58) later went on to work for the pharmaceutical industry (Figure 2). Among all industry presenters, we found that 12% (n=21) had previously

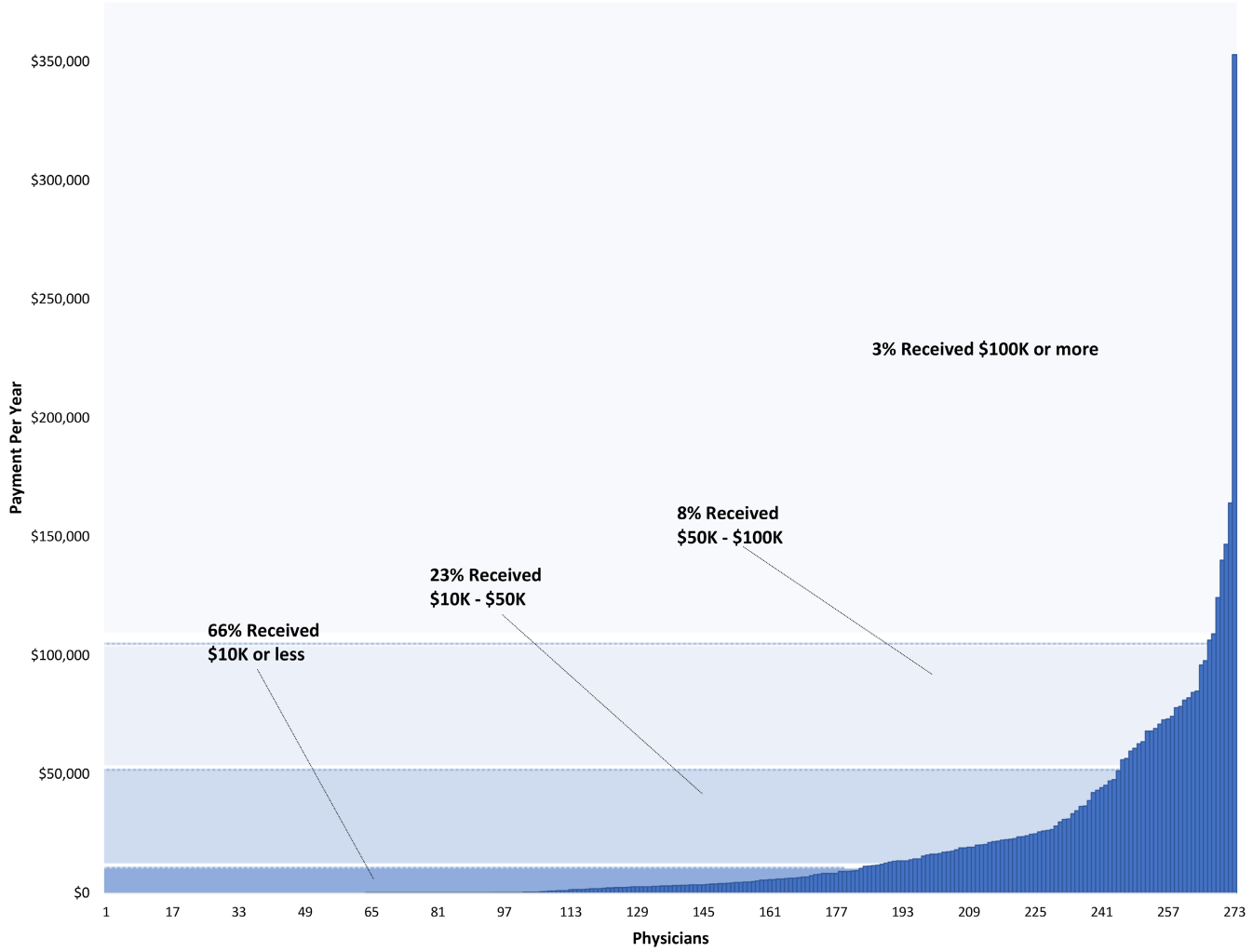

FIGURE 1 Average yearly general payments received by US-based physician presenters, moderators and panellists.

worked at a regulatory agency. Among 502 presenters in whom revolving door politics could apply, 16% ($n=79$) spent time both on the regulator and industry side.

Among regulatory presenters who went on to be employed by industry, 95% were FDA ($n=55$) and the remaining 5% ($n=3$) were representatives from the European Medicines Agency (EMA). The average time individuals were employed by the FDA or EMA prior to entering the pharmaceutical industry was 8.3 years.

3.5 | Disclosures

Presentation slides, recordings or transcripts were readily available for 32% ($n=12$) of the workshops. The webpages for the remaining 68% (n = 25) were behind a paywall or require a fee for registration, contained broken or incorrect links or contained no detailed information about the presentations. Of 92 presenters for which we were able to obtain detailed meeting information, 50% ($n=46$) had a disclosure slide or verbally indicated their disclosures. Of these, 22% ($n=10$) reported no conflicts, 57% ($n=26$) reported research funding from industry, 50% ($n=23$) reported consulting payments, 7% ($n=3$) reported being a founder of a company, 17% ($n=8$) reported honoraria, 37% ($n=17$) reported being on an industry advisory board, 15% ($n=7$) reported stock and 2% ($n=1$) reported a spousal employment conflict (Table 3).

Among those who reported no conflicts of interest, 30% ($n=3$) had previously received payments from the industry according to the Open Payments database. Two of these individuals received average payments below $100/year, while one individual received an average yearly payment of $21,868 USD. Among those who did not present a disclosure slide or verbalize disclosures, 33% ($n=15$) had previous payments from the industry. This group received an average yearly general payment of $13, 211 and a median of $2145. Average yearly research payments were $964, median yearly research payments were $0.

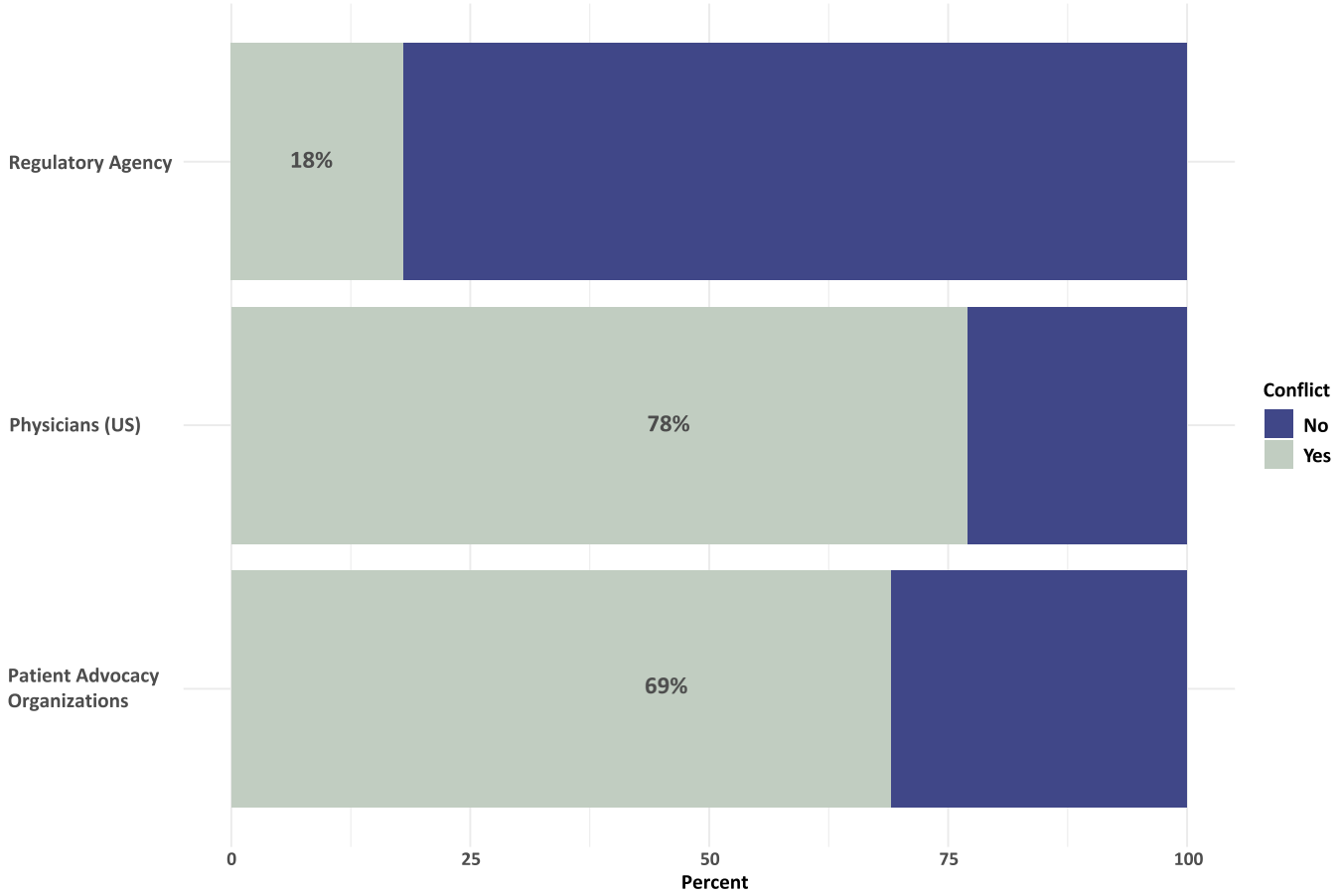

FIGURE 2 Percentage of presenters, panellists and moderators with a conflict of interest among US physicians, representatives of regulatory agencies and representatives of patient advocacy organizations.

4 | DISCUSSION

Workshops involving members of regulatory agencies and many other interested parties are important for advancing the fields of haematology and oncology by helping to shape future directions of treatments and research. Individuals participating as presenters, moderators and panellists are central to guiding discussions and may influence future directions of the fields.

Previous studies have examined the FCOI that exist in FDA advisory committee meetings, showing that financial ties to industry can bias voting behaviour[9] and is common among public speakers.[4] Our study complements these works, providing insights into the conflicts of interest in a different setting. Workshops are different than advisory meetings because they do not pertain to specific drug products, and are not immediately related to drug approval, yet, they play a vital role. Workshops hosted by or with the FDA bring a diverse set of stakeholders together, including well-regarded experts, to discuss challenges facing the field, new treatment strategies, regulatory strategies and clinical trials. These workshops often shape the precedents that define the FDA's broader strategy in a regulatory space, which some scholars believe is the most important role of the agency.[10]

People who serve on advisory committees for the FDA are not allowed to have a direct conflict of interest, yet it is unclear if these rules apply to individuals who present at the workshops. In our search of slides and meeting information, we were unable to find any information indicating whether this was a consideration.

Our research primarily focused on the conflict of interest of presenters who were US physicians, yet there were a number of presenters with other degrees, including PhDs, who were not included in the analysis of payments, as these data were not available. The exclusion could limit the generalizability of our results because we were not able to determine payments for them. We feel that a focus on those with medical degrees may be more relevant from the patient's perspective because they are often practising physicians, who play a key role in the intersection between patients, industry and regulators.

Our study has 5 key strengths: First, ours is the first to examine the conflicts of interest in the context of FDA

TABLE 3 Conflicts of interest disclosed by presenters at hem/oncology FDA joint workshops ($N = 46$[a]).

	No conflict	Research funding	Consulting	Founder	Honoraria	Advisory Board	Stock	Spouse
Physicians (US)	6	24	17	3	8	16	7	1
PhD	4	2	4	0	0	1	0	0
Other clinical[b]	0	0	1	0	0	0	0	0
Other non-clinical[c]	0	0	1	0	0	0	0	0
Total no. (%)	10 (22%)	26 (57%)	23 (50%)	3 (7%)	8 (17%)	17 (37%)	7 (15%)	1 (2%)

[a]Presenters who listed multiple types of conflicts were counted in multiple categories.
[b]Includes nursing and pharmacy degrees.
[c]Includes individuals with business, law or no degree listed.

joint workshops. Although we focused on haematology and oncology, we are confident future investigators will broaden this work to other domains.

Second, our work suggests that the majority (78%) of US-based physicians who participate in haematology and oncology workshops held jointly with the FDA have received at least one payment from the industry in the last 5 years, with a mean yearly general payment of $16,434 and a median of $2981. These exceed the mean payment of $7750 and the median payment of $632 per year for an average physician in the field.[11] In addition to the important expert perspectives physicians provide during presentations and panel discussions, they also play a critical role in the implementation of new drugs into clinical practice. Given their prominence and ability to guide the field, a more representative selection of physicians without FCOI with industry may help to promote unbiased discussions at workshops.

Third, we found that 69% of presenters involved in patient advocacy were affiliated with an organization that received funding from the pharmaceutical industry. This finding builds upon prior works which have shown high a prevalence of industry-funded patient advocacy organizations in the United States.[12,13] Given the unique and essential perspectives patient advocacy groups provide and the critical roles they play in advancing policy, it is important to consider the potential for industry funding to unintentionally influence their priorities and the perspectives they share. A greater number of patient advocacy organizations without financial ties to the industry should be represented at workshops. Additionally, there is currently inconsistent reporting of industry funding to patient advocacy organizations, and it is often challenging to access, relying largely on self-reported financial details the organization provides or tax information. Greater transparency of funding sources is needed to better assess the FCOI of patient advocacy organizations.

Fourth, our findings on the revolving door between regulatory agencies represented at the workshops and the pharmaceutical industry expand upon prior work that showed over 50% of haematology-oncology reviewers representing the FDA between 2001 and 2010 were employed by the pharmaceutical industry after their service.[14] We found that 16% of workshop participants representing a regulatory agency went on to work for pharmaceutical companies, and an additional 12% of those representing pharmaceutical companies had previously worked as regulators. These findings support the claim that members of the FDA continue to leave their roles in pursuit of a career in the very industry they previously regulated. Moreover, the fact that those in our study worked for a regulatory agency an average of 8.3 years before leaving to work in the industry suggests it is not a career change after a short

period of time, but rather, a decision made by those with more knowledge and experience working in the regulatory system. While this is not a direct conflict of interest, it is of concern because it has the potential to introduce bias in regulatory decision-making if regulators are considering pharmaceutical companies as future employers.

Fifth, when examining the conflicts of interest disclosed during presentations at the workshops, we note that there were challenges in even accessing the materials. We were only able to access slides, transcripts or recordings for 12/37 (32%) workshops. While a request could be made to obtain this information, we suggest that it would be in the best interest of the public if the information were made readily available and easy to access. We also found that among the presenters we were able to characterize based on meeting materials, only 50% presented a disclosure slide or verbalized their COIs. This suggests inconsistencies or leniency in COI disclosure policies in these workshops. Further, we found that COI disclosures among presenters were not always consistent with the information we obtained from CMMS Open Payments for those who were US-based physicians.

4.1 | Limitations

Limitations of our study are primarily due to the constraints of publicly available information. Our assessment of FCOI in the form of industry payments was limited to US-based physicians as there are currently limited data available on industry payments to physicians outside of the US. Additionally, we did not assess the amount of funding received by each patient advocacy organization and we were only able to collect information if it was reported by the organization on their website or if 990 tax forms were available. Therefore, the number of organizations that received funding may be an underestimate. We also did not examine other ties patient advocacy organizations may have to industry through their board members or other affiliations. We were also unable to access presentation materials or recordings for nearly 70% of the workshops in our study. Therefore, our ability to determine how consistently COIs were disclosed for the entire study population is limited. Lastly, we relied on information reported on PubMed, LinkedIn or Google to determine current and prior employers of individuals representing the FDA and the pharmaceutical industry. While a thorough search was undertaken, it was not always possible to assess the employment history of each individual. It's therefore possible that we have underestimated the number of individuals who were employed by both the FDA and the pharmaceutical industry throughout their careers.

5 | CONCLUSION

Presenters and panellists at haematology-oncology workshops hosted by or held jointly with the FDA involve multiple stakeholders that may help guide future directions of treatment strategies and drug development by providing a platform for regulators, experts and patient advocates to engage in discussion. Our findings support the need for clear disclosures of FCOI at FDA workshops held in collaboration with other organizations and suggest that using FCOI information where available may be helpful in selecting a balanced, unbiased panel of presenters.

AUTHOR CONTRIBUTIONS

Miller and Haslam had full access to all of the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: Prasad. Acquisition, analysis or interpretation of data: Miller, Haslam. Drafting of the manuscript: Miller, Haslam. Critical revision of the manuscript for important intellectual content: All authors. Statistical analysis: Miller, Haslam. Supervision: Prasad.

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CONFLICT OF INTEREST STATEMENT

Dr. Haslam and Ms. Miller reported being employed through funding to their institution from Arnold Ventures LLC. Ms Miller reported prior employment through Novartis AG and Genentech, Inc. Dr Prasad reported receiving research funding from Arnold Ventures LLC during the conduct of the study; royalties for books and writing from Johns Hopkins Press, MedPage and the Free Press; consulting fees from UnitedHealthcare and OptumRX; and 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.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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