Industry-sponsored meals are associated with increased prescriptions and Medicare expenditures on brand-name colchicine in the United States

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Introduction
Colchicine has been used for treatment of gout for many decades without formal approval in the United States (US). However, the US Food and Drug Administration approved Colcrys (colchicine) and 3-year market exclusivity to the manufacturer based on a one-week trial of 185 patients in 2009 under the Unapproved Drug Initiative program.1 This approval allowed the manufacturer to significantly increase the price of the drug from less than $0.50 per pill to $5.00 per pill, effectively monopolizing the market.1 Furthermore, the substantial increase in colchicine prices has resulted in a 283-fold rise in healthcare expenditures1 and potentially poorer disease control.2

Previous studies3 demonstrated that payments from pharmaceutical companies to physicians are associated with increased use and healthcare costs for long-established drugs, whose prices have been significantly
raised by the pharmaceutical companies, such as repository corticotropin. This study aimed to examine the associations between payments from the manufacturers of brand-named colchicine to physicians and physicians’ prescribing patterns of colchicine in the US.

Methods

This cross-sectional analysis of the Centers for Medicare & Medicaid Services (CMS) Medicare Part D data linked to the CMS Open Payments Database and Physician Compare database, previously performed. All physicians who reported 10 or more claims for generic or brand-name colchicine (Colcrys and Mitigare) in any year from 2014 through 2021 were extracted from the CMS Medicare Part D Public Use Files. As previous studies showed that meal payments from the healthcare industry strongly associated with physicians' prescribing patterns, all meal payments from the two manufacturers of brand-name colchicine (Takeda Pharmaceuticals and Hikma Pharmaceuticals) to the physician prescribers were extracted from the Open Payments Database between 2014 and 2021.

Associations between payments and the prescriptions of brand-name colchicine were evaluated using multivariable population-averaged logistic generalized estimating equations (GEE) at individual physician level. Associations between the receipt of meal payments and the proportion of prescriptions of brand-name colchicine relative to all colchicine prescriptions were examined with logistic GEE. Furthermore, associations between the annual number of payments and annual number of 30-day standardized claims and Medicare spending were evaluated with multivariable linear GEE. All models were adjusted for the covariates such as gender, geographic region, years from medical school graduation, the graduated medical schools, specialty, and payment year. Supplemental Material describes the details of data collection and analyses processes.

Results

A total of 54,836 physicians reported more than 10 claims for colchicine between 2014 and 2021. Among them, 79.9% were primary care physicians specializing in family practice, general internal medicine, and hospitalist. 44.9% and 8.0% of physicians received one or more meal payments from Colcrys and Mitigare manufacturers between 2014 and 2021, respectively. The average payment per meal was $14.9 for the Colcrys manufacturer and $15.1 for the Mitigare manufacturer. Receipt of meal payments from each manufacturer was associated with higher odds of prescribing Colcrys (odds ratio [OR]: 1.24 [95% CI: 1.21–1.27], p<0.001) and Mitigare (OR: 3.54 [95% CI: 2.98–4.20], p<0.001) in the year the meal was provided to the physicians (Table 1). Furthermore, the receipt of meal payments was significantly associated with a higher proportion of prescriptions for each brand-name colchicine relative to all colchicine prescriptions for Colcrys (OR: 1.20 [95% CI: 1.18–1.23], p<0.001) and Mitigare (OR: 2.70 [95% CI: 2.24–3.22], p<0.001).

One increase in the number of meal payments from the manufacturers was significantly associated with an increase in the number of claims of 0.26 (95% CI: 0.23–0.30, p<0.001) for Colcrys and 0.54 (95% CI: 0.10–0.89, p=0.01) for Mitigare (Table 1). Consequently, one increase in the number of meal payments was associated with higher Medicare spending of $55.4 (95% CI: $48.3–$62.5, p<0.001) for Colcrys and $153.7 (95% CI: $17.7–$289.6, p=0.03) for Mitigare.

Discussion

The study findings indicate that meal payments provided by the manufacturers of brand-name colchicine to prescribing physicians were associated with increased prescribing rates and higher Medicare spending related to brand-name colchicine. Physicians who received meal payments were more likely to prescribe brand-name colchicine compared to those who did not. While the prices of generic colchicine were set by the manufacturer of the brand-name colchicine, they were lower than those of the brand-name colchicine. Consistent with previous studies, the study suggests that industry-sponsored meal payments may contribute to the recent significant increase in healthcare costs associated with colchicine, which has brought little benefit to patients due to the formal approval.

This study contains several limitations. This cross-sectional analysis showed the associations, but not causality. Due to privacy protection, data with fewer than 10 claims and patient demographic information were
not available. There was the possibility of inaccuracies in the databases.\(^6\)

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I would like to thank Ms Megumi Aizawa for her dedicated support of my research. For drafting parts of the presented text, the author used the pre-trained ChatGPT (version 3.5) model developed by OpenAI in order to check and correct the manuscript for spelling and grammatical errors. I checked and edited the text for unintended plagiarism, and verified all facts, values, and references that I used from the ChatGPT outputs before the manuscript submission.

**References**


Table 1. Associations between meal payments from the manufacturers of brand-name colchicine and physician prescribing patterns for colchicine in the United States

<table>
<thead>
<tr>
<th>Variables</th>
<th>Receipt of</th>
</tr>
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<tbody>
<tr>
<td>Prescriptions of each brand-name colchicine (95% CI), OR</td>
<td>Colcrys(^a)</td>
</tr>
<tr>
<td>Percentage of prescriptions of each brand-name colchicine relative to all colchicine prescriptions (95% CI), OR</td>
<td>Mitigare(^b)</td>
</tr>
<tr>
<td>Number of 30-day standardized claims including refills (95% CI), n</td>
<td>One increase Colcrys(^a)</td>
</tr>
<tr>
<td>Medicare costs (95% CI), $</td>
<td>Colcrys(^a)</td>
</tr>
</tbody>
</table>

Legend: \(^a\) The associations were examined between 2014 and 2021. \(^b\) In 2014, Takeda Pharmaceuticals, the manufacturer of Colcrys, filed a lawsuit with the US Food and Drug Administration and obtained a temporary restraining order against Hikma Pharmaceuticals, the manufacturer of Mitigare. Marketing of Mitigare was then resumed in January 2015. Therefore, the study examined the association between meal payments and Mitigare prescriptions from 2015 to 2021.

Abbreviations: 95% CI (95% confidence interval), OR (odds ratio). *p<0.05, **p<0.001.