Economists & Accusations - Supporting Patients by Rebuking Dafny et al.

Unethical economists have recently published an article attempting to stop pharmaceutical companies from providing charities with donations. They see this as inducement and argue that it could impact patients negatively by raising the cost of care. However, there are several errors in their publication. Leemore Dafny, Christopher Ody, & Teresa Rokos published their article in Health Affairs 41, No 9 (2022) in September, and the absence of economic ethics was placed on full display. In Dafny et al.'s, ***Giving a Buck or Making a Buck? Donations by Pharmaceutical Manufacturers to Independent Patient Assistance Charities***, the authors attempted to prove that the pharmaceutical industry and charities were engaged in illegal activities in violation of current law, specifically inducement. In this rebuttal, we aim to outline the shortcomings of the authors' flawed arguments & ensure everyone understands the impact of the inducement claims. Dafny et al. attempted to put data to use to introduce flaws in current law. However, it's the very data & its backers that prove this was an unmitigated hit piece on charity by the insurance industry. We will utilize this article to put the flaws of their argument on display, help educate the public & bring readers' focus where it should be: on improving patient care & outcomes. To do so, we must start with current law, specifically inducement.

Inducement

> "*Inducement was codified into law in section 1128(a) of the Social Security Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Inducement [occurs when] a person…offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services.*" [1]

Dafny et al. attempt to argue that pharmaceutical organizations' providing donations to charities who in turn blindly provide aid for patient care is inducement. These are very serious accusations by Dafny et al., both for the immense financial liabilities that parties would be required to pay as remuneration for the inducement, and the ceasing of pharmaceutical industry donations to charities and patient advocacy organizations. We will explore the accusations by Dafny et al. in detail and discuss the error in methodology, the correlation taken for causation in the data analysis, and how authors' proposed outlawing of pharmaceutical donations

[1] https://oig.hhs.gov/documents/special-advisory-bulletins/886/SABGiftsandInducements.pdf

would impact patients now & into the future, a nearly $2 billion dollar shortfall to these patient-focused charities.[2] Let's begin with an evaluation of the methodology.

Methodology & Evaluating Rare-Disease: Mistakes or Intentional Errors?

Dafny et al. utilized blinded data sets to attempt to identify and prove inducement by evaluating rare-disease markets. They note, "Using claims data for a sample of roughly one-third of Medicare Advantage (MA) enrollees in 2010 and 2017, we examined the scope of these charities and the financial incentive for manufacturers to donate to them."[3] Dafny et al. began the overview of their study providing insights on the fill rate of medications published by IQVIA. As the team notes,

> *A 2018 IQVIA report found that 27.6 percent of new prescriptions for all branded drugs were abandoned within thirty days by Medicare enrollees facing $50 in cost sharing compared with fewer than 10 percent at $0 in cost sharing and more than 50 percent at greater than $125 in cost sharing. Although estimates of prescription abandonment vary by drug type and disease, these data suggest that even relatively small amounts of patient assistance could result in a sizable increase in use.* [4]

It is this premise that the authors hope pushes you further towards their conclusion rather than the data they had at their disposal. As noted, the data included *"MA claims data from the Health Care Cost Institute (HCCI) with data on conditions covered by the seven largest independent patient assistance charities in operation between 2010 and 2017."* [5] More on HCCI to come shortly. The authors go on to explain how it's important to note that the data set they were in possession of,

> *"did not [include] which patients…received charitable assistance or which manufacturers made donations… However, we were able to evaluate manufacturers' financial incentives by calculating patients' cost sharing and manufacturers' revenues on claims likely to be eligible for assistance."* [6]

They also note, *"Because we did not observe which patients were financially eligible to apply for assistance, we could not identify which claims were in fact assistance eligible."* [7] These are critical facts. The authors were unable to evaluate the claims at a patient level to understand a patient's need for support vs those that

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[2] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

[3] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

[4] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

[5] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

[6] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

[7] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

received support. However, they claim manufacturers are benefiting through donating to charities to gain access to patients that would otherwise not receive the manufacturer's medication (again, unfounded).

Dafny et al. evaluated claims data provided by HCCI to analyze 87 different conditions recognized in ICD-9 coding in 2010 and 154 conditions recognized in 2017's ICD-10 coding (system updates which are not apples to apples). The authors used the charities' websites as well as the FDA published approved medications with their approved diagnoses to understand assistance eligibility. Eligibility, by law, requires that the patient have an approved diagnosis in concordance with the FDA approved label for the medication. If there is an approved diagnosis and the patient meets the threshold for financial assistance established by the charities, they can hypothetically apply for the funds. The authors note how they utilized the claims data in detail, including:

> *"We identified claims as potentially assistance eligible if they pertained to a person with a charity-covered condition and a drug approved to treat that condition. Because we did not observe which patients were financially eligible to apply for assistance, we could not identify which claims were in fact assistance eligible. However, we were able to identify and exclude enrollees who were dually eligible for Medicare and Medicaid; such enrollees accounted for 0.75 percent and 10.2 percent of enrollees with potentially assistance-eligible claims in 2010 and 2017, respectively (according to authors' calculations of the HCCI data). Although dually eligible enrollees may qualify for assistance, their cost sharing is likely to be minimal, and thus they may be unlikely to apply for assistance. The same is true for the approximately 2.8 percent of Medicare enrollees who receive Medicare's low-income subsidy but are not dually eligible, although these enrollees were not identifiable in our data. At the other end of the income distribution, applicants with income in excess of thresholds are ineligible to receive assistance."*[8]

To put the above into layman's terms, *they did not have detailed claims data to align patients who received funding with the approved diagnosis and proof of need of funding*. Using the HCCI data, they authors threw out the patients who were ineligible due to law such as those that are eligible for both Medicare & Medicaid, patients enrolled in Medicare who receive Medicare's low-income subsidy but do not qualify for Medicaid, and patients who make too much money. Therefore, to summarize, the authors utilized a dataset and attempted to compare 2010 and 2017 datasets that are not even close to the same due to the immense growth in code sets between ICD-9 & ICD-10, and only looked only at patients that were eligible for assistance.

Yet, Dafny et al., go on to note the current laws,

> *"…the manufacturer cannot earmark the donations for its own drugs. We defined the breakeven inducement percentage as the percentage of sales that must be induced to render profitable a donation*

[8] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

that is not earmarked for the donor's drug but is earmarked for a specific condition treated by the donor's drug."[9]

I will say that again for those seated in the back of the room, "the manufacturer cannot earmark the donations they provide to charities for their own drugs." That is inducement! That would be a "quid-pro-quo" (I give you money for you to get me the patients) and would violate inducement & anti-kickback statutes. The authors have put a hole in their argument yet nonetheless, they continued:

"For the manufacturer to find it profitable to cover cost sharing for all drugs treating the condition, the donation would still need to induce at least $500 of total spending per patient with the condition (that is, not only those taking their drug). Thus, $500/$2,500 = 20 percent of observed revenues per patient with the condition would need to be induced to render a donation breakeven; equivalently, the assistance would still need to induce 10 percent more spending on the manufacturer's drug, which translates into 20 percent greater spending by the 50 percent who take it…As this scenario shows, the breakeven inducement percentage will tend to be lower for manufacturers whose drugs have higher market shares within a covered condition. It will also tend to be lower for manufacturers of high-price drugs because patient cost sharing is generally a smaller percentage of the total cost of high-price drugs as a result of the prevalence of fixed copays and the greater likelihood that patients receiving high-price drugs will exceed their deductibles and out-of-pocket limits. "[10]

Let's break this part down further. The authors are attempting to set up a hypothetical condition of illegality. Their framework evaluates the amount of money that would be donated, compared to the amount they would make based off drug utilization and payment by the insurance company (if there is a payment at all, as many of the payments made by patients are for deductibles and coinsurance). Their analysis claims that by giving the charity the money to support patients, as long as there was a 10% increase in use of the drug, the drug manufacturer would see 20% greater spending on their products by those that fill their prescription (the 50% that take it). Finally, the statement made by the authors about "*higher priced drugs leading to lower patient expense due to fixed cost sharing*" is just not correct.

A patient's insurance plan typically includes a deductible, a copay, and coinsurance. A *copay* is a fixed amount paid for a drug or service. That is not something typically seen in the pharmaceutical world. However, the patient's deductible (a set amount the patient has to pay before their plan's benefits kick in) and coinsurance (a percentage of the billed amount that is the patient's responsibility after the deductible has been met) are set for all healthcare delivered services and drugs. The price of said product has no bearing on the plan and higher-cost drugs have a higher likelihood that the patient would be responsible for fulfilling their full deductible and coinsurance until they hit the plan's out-of-pocket maximum for the year - or $18,200 for

[9] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

[10] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00177

2023.[11] Perhaps the authors would like to address how paying over $18,000 for a drug because it's a high-priced product is a benefit to patients?

Errors, Issues & Glaring Limitations

We have already discussed the limitations not transparently laid out by our authors, including the differences in ICD-9 & ICD-10 code sets, their assumptions of higher priced products having less financial impact on patients, and clearly laying out that due to ***anti-kickback statutes***, the inability for a drug manufacturer to earmark funds for their drug alone. However, we must also dive into the code set being utilized by Dafny et a., the HCCI database.

HCCI or The Health Care Cost Institute, claims to be committed "to get[ting] to the heart of the key issues impacting the U.S. health care system — by using the best data to get the best answers. HCCI stands for truth and consensus around the most important trends in health care, particularly those economic issues that are critical to a sustainable, high-performing health system."[12] It's great that HCCI is committed to getting to the heart of the key issues impacting the US health care system, as they are backed by four health insurance & data companies that contribute the claims data Dafny et al. utilized in their report. The entities that back HCCI include Aetna, Humana, Kaiser, and Blue Health Intelligence. These organizations alone account for the health insurance coverage of 49% of all patients in 2022.[13] HCCI utilizes the data and funding provided by these organizations to take part in lobbying efforts. Though data does not have a side, it's obvious that HCCI is committed to the interests of health insurers. The problem for the authors is that brings the data & the article overall into new light.

Rare-disease is the costliest of all treatment areas in healthcare. Some of the drugs in the space, like Novartis' *Zolgensma*®, can cost as much as $2.1 million (this was the recommended price by the often strict non-government entity known as The Institute for Clinical & Economic Review or ICER).[14] What this reporting unveils is truly an attempt at an unmitigated hit piece on organizations that assist patients with rare-disease in affording the life-changing (and in some cases -saving) medications they need. If HCCI really wants to focus on the issues impacting the US healthcare system the most, perhaps they can start with investigating the Pharmacy Benefits Managers' role in healthcare, or even get the insights of the patients that require the

[11] https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/

[12] https://healthcostinstitute.org/about-hcci

[13] https://www.fiercehealthcare.com/payer/aetna-humana-kaiser-unitedhealthcare-team-up-to-trend-claims-data

[14] https://www.forbes.com/sites/johncumbers/2021/12/16/why-some-drugs-cost-21-million-per-dose-and-how-one-company-plans-to-change-this/?sh=886c38589536

assistance of charities to afford their medications to share the voice of the patient? This is a major red flag in our minds and something that should be transparently discussed by the authors.

Dafny et al. also presented their own interpretation of a few limitations, including:

> *Our analyses had a number of limitations, and we made several simplifying assumptions. First, in calculating breakeven inducement percentages, we assumed that manufacturers would fully fund patient cost sharing and that there were no maximum assistance limits per patient. These simplifications increase the amount of donations required to offset patient cost sharing, thereby increasing estimated breakeven inducement percentages—that is, generating more conservative estimates of inducement required for a manufacturer to break even from a donation.*

It's quite obvious that the authors do not understand the pharmaceutical industry. All patient assistance funds have cost sharing / funding limits and annual maximums for patients. Charities also run into budget shortfalls for patients quarterly and monthly, if not weekly in some cases! As of publication, the Patient Access Network Foundation (PAN Foundation), an organization that helps patients in nearly 70 different disease states gain access to critical funding, had only 21% of its disease state funds open for patients to apply.[15]

Patient Assistant Charities, The Law & The Patient Voice

The authors of this paper cherry-picked data sources that told the desired story they sought & shared the one true inducement story out of the patient charity world in over a decade of patient engagement. Dafny et al., shared the story of the Caring Voices Coalition, attempting to brand it as the normal ways of working for all patient charities. In 2018, the Caring Voices Coalition was shut down by the Health & Human Services' Office of The Inspector General (OIG) after over 15 years of helping over 100,000 patients: *"United Therapeutics Corp agreed to pay $210 million to resolve the claims that it used the Caring Voices Coalition as a conduit to cover Medicare patients' out-of-pocket drug costs, in order to eliminate price sensitivity and to boost sales."*[16] This had been legally found to be inducement, and as such, organizations should have been made to pay. Both the pharmaceutical organization that was found responsible and the charity were forced to pay restitution, while in the case of the Caring Voices Coalition, the charity was not able to survive the bad press & was forced to shut down. This incident also resulted in strict oversight by pharmaceutical compliance teams, regulatory agencies, and the United States Department of Justice to track all restricted & unrestricted grants, while accounting for every dollar spent.

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[15] https://www.panfoundation.org/find-disease-fund/

[16] https://www.reuters.com/article/us-usa-healthcare-charity/drug-charity-halts-patient-aid-after-u-s-health-agency-pulls-approval-idUSKBN1EU1V6

The Potential Impact on Patients

There are dozens of Patient Assistance Charities that are helping patients with medicines and treatments in the US. These charities follow strict guidelines for transparent & ethical practices, providing millions of dollars to underserved populations each year. These organizations have a duty to the law and their patients – not just preserving the rights of the patient but also protecting the rights of the donor. HCCI's report failed to recognize this, instead opting for a one-sided narrative that reinforces their efforts to portray charities as bad actors in US healthcare, driving up the cost of care.

We believe it's important to include the voice of the patient in this discussion. Patients understand their own struggles better than anyone and therefore should be heard when discussing patient assistance charities. The authors could have interviewed or surveyed patients who receive help from these charities to gain a true understanding of how helpful they are, rather than relying solely on data from a skewed source. Patients should be at the center of any discussion related to charity care, and their voices should be included in decisions that affect them.

Lastly, patient assistance charities are a critical lifeline for people living with chronic diseases who can't afford medications without assistance. It's important to remember that these organizations have historically been founded by families impacted by different medical conditions, looking to ensure other families never have to go through the pain & trauma they had gone through. When you look at the rare disorders that Dafny et al. reviewed, these are conditions where there may be only one or two therapies available. To say that utilization of a therapy in rare-disease is a sign of inducement is ludicrous. These are patients who have waited, in some cases, decades for a treatment to help them. It's no surprise that when that therapy comes to market there will be patients lining up for it. However, the affordability piece is always an issue in rare-disease & should not be taken lightly. No patient should ever be held from a life-changing product & God bless the charities that are there to help these patients. Ultimately, drug pricing is an issue that must be tackled head-on, but not at the expense of charities and ***definitely not at the expense of patients***.