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DISCLOSURES

Michael Chernew and Mark Fendrick provide consulting services to Hewitt Associates LLC and ActiveHealth Management related to value-based insurance design, and accept consulting fees and speaking honoraria related to value-based insurance design. Allison Rosen is employed by the University of Michigan's Center for Value-Based Insurance Design. Wegh, Rosenberg, and Juster are employed by ActiveHealth Management, which provides consulting services to employers, health plans, and pharmacy benefit managers. Shah is no longer affiliated with ActiveHealth Management. The study referred to in the JMCP editorial and this letter was supported by GlaxoSmithKline and Pfizer, and the Center for Value-Based Insurance Design lists 6 pharmaceutical manufacturers as supporters.

All authors were responsible for the study concept and design of this response to an editorial. All authors shared equally the data analysis, data interpretation, writing, and revision.

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The Editors Respond Regarding the Shortcomings in Reported Research on Value-Based Insurance Design

We thank Chernew and colleagues for their response to our editorial on value-based insurance design (VBID)¹ and for their stated commitment to health care system improvement. Of course, in making improvements to prescription drug benefit designs in an effort to improve compliance, the key question is not *whether* it is desirable to encourage patients to be adherent with chronic medication therapy; any reasonable observer would agree that patients should be encouraged to take medication as prescribed. The key questions are (1) whether the proposed benefit design change(s) improve compliance to a degree that affects patient outcomes, and (2) whether the additional expenditure associated with the change is efficient, that is, whether it allocates resources in a way that maximizes their value or wastes resources that could better be spent elsewhere. Put simply, the key question is what outcome(s) a health plan "buys" when it lowers copayments, thereby increasing its net cost for prescription drugs.

Unfortunately, no one really knows the answer to that question, and Chernew et al.'s work provides little, if any, of the needed insight. Like their original research article,² their letter is regrettably more notable for what it omits than for what it says. Among the important issues raised by Fairman and Curtiss, but unaddressed by the authors' letter, are:

- 1) whether the medication possession ratio effect estimated by Chernew et al., an added 7 to 14 days of therapy annually, could reasonably be expected to have any impact on patient outcomes;
- 2) whether the study's results reflect selection bias associated with open enrollment, in which members with a choice of plan (e.g., spouse's insurance) who anticipate a high level of compliance with chronic medication use in the coming year naturally gravitate toward the plan in which drugs are available at a lower copayment;
- 3) what the actual total cost of the intervention was; and
- 4) whether key characteristics of the 2 employer plans and beneficiaries (e.g., formulary content, pharmacy benefit design features, industry sector, beneficiary-to-employee ratio, baseline expenditures, and levels of chronic disease) would have supported Chernew et al.'s view that their study results are valid and relevant to health plans making decisions about benefit designs, had these critical details been included in the Chernew et al. research report.

While we do not oppose VBID in concept, we await the findings of research to determine its effectiveness, since to date controlled research evidence does not support it. As Fairman pointed out in her editorial review of cost-sharing in the January/February 2008 issue of *JMCP*, the assertion that commercially insured beneficiaries are price-sensitive in adherence to chronic medications is based largely on studies with weak cross-sectional research designs. Controlled studies of typical copayment increase amounts in commercial populations have documented modest effects on utilization overall and little or no impact on adherence to chronic medication.³ We are aware of only 1 study of out-of-pocket (OOP) cost reduction and adherence prior to the Chernew et al. analysis. Using a quasi-experimental (pre-post with comparison group) design, that study found that providing free glucose test strips to patients with diabetes “shifted costs from patient to health plan, without improving adherence” in blood glucose monitoring.⁴

While we await studies of the effect of reducing copayments for brand drugs, payers can reduce patient OOP cost by promoting the use of generic medications. Generic drugs are available in most chronic therapeutic classes and in all the classes studied by Chernew et al. (except inhaled corticosteroids, for which there was no significant association between the benefit design and adherence), for a mean OOP cost of \$11 per prescription in nationwide employer-sponsored plans in 2006⁵ and \$5 per prescription in Chernew et al.’s intervention plan.²

We do not understand Chernew et al.’s assertion that our editorial inaccurately attributed to them statements made by others. Our editorial directly quoted Chernew et al.’s original research article and the press release put forth by the University of Michigan, which houses the Center for Value-Based Insurance Design.^{1,2,6} These quotations included Chernew et al.’s statements that “...we expect health improvements, although we do not quantify them in this study,” and that because of the intervention, “there might be gains in worker productivity or reduced absenteeism or disability.”² As we noted in our editorial, Chernew et al.’s report provided neither citations to published research nor study findings to support these statements.¹ In that vein, we find it troubling that the University of Michigan’s press release described the Chernew et al. analysis as a “rigorous, controlled trial,”⁶ a term that erroneously implied randomization in an analysis that was in fact not randomized.

We are also disappointed by Chernew et al.’s persistent refusal to present critical data about their study groups, especially since, as we pointed out in our editorial, the small amount of information presented in the study report suggested that the study groups were very different at baseline (e.g., mean age difference of 7 years, baseline cost-sharing per generic claim of \$5.00 and \$16.22 for intervention and comparison groups, respectively).^{1,2} Whether the comparison group (“Company B”⁶) is adequate to represent what the experience of a true control group would have been (i.e., had beneficiaries of “Company A”⁶ been randomized to

intervention and control groups) remains unknown. Transparent disclosure of fundamental factors, such as the actual pharmacy benefit designs, formulary content, and baseline health-related information (e.g., utilization, chronic disease) for the 2 study groups would have enabled readers to decide for themselves whether the effects claimed for this VBID intervention are based on a valid analysis that provides relevant information for their health plans. As threats to the internal validity of trend analyses of non-randomized groups (e.g., possible selection bias associated with the intervention; the possibility of “selection maturation” effects that could be associated with different levels of chronic disease) are well known,⁷ we dispute Chernew et al.’s contention that their analyses are valid despite baseline differences, and we remain concerned about lack of disclosure. Chernew et al.’s dismissal of legitimate questions about the missing information with the statement that transparency “would not change the results” is both unhelpful and inconsistent with basic standards for the reporting of research results.^{8,9}

The feedback that we have received from health plans in response to our editorial suggests widespread frustration regarding the abundance of hype without substance regarding VBID. Mindful of what Chernew et al. describe as a “proliferation of VBID products,” we continue to urge both the conduct of better-controlled studies of cost-sharing decreases and appropriate caution in the adoption of untested benefit designs described as innovations.

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DISCLOSURES

The editors report no conflict of interest on this subject.

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