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## **Table 7:** Estimated effects of proposed reforms on US national pharmaceutical expenditures, 2017

### Savings from lowering drug prices

$360.1 billion: Total current retail prescription drug expenditures[a]

$51.0 billion: Retail drug expenditures by discounted payers (Medicaid, the VA and other non-Medicare federal programs).

14%: Percent of retail drug spending by discounted payers ($51.0 billion/$360.1 billion)

28%: Percent of total drug expenditures that are non-retail[b]

$500.1 billion: Total (retail + nonretail) drug spending ($360.1 billion / [1 - 0.28]).

$429.3 billion: Total drug spending by non-discounted payers ($500.1 billion – [$500.1 billion * 0.14])[c]

72%: Percent of national drug expenditures on brand-name drugs[d]

$309.1 billion: Total drug spending by non-discounted payers on brand-name drugs ($429.3*0.72)

50%: Estimated average reduction in brand-name drug prices[e]

**$154.6 billion: Savings from reduced brand-name drug prices** (0.50 x $309.1 billion)

### Costs from increased utilization due to new coverage for uninsured persons

28 million: Number of persons uninsured[f]

$813: Increased prescription drug spending per newly insured person[g]

**$22.8 billion: Increase in prescription drug spending for newly insured persons** (= $813 x 28 million)

### Costs from increased utilization due to the elimination of cost-sharing for persons who are currently insured

17%: Estimated percent increase in utilization of outpatient prescription drugs by previously-insured persons due to the elimination of cost-sharing[h]

**$52.9 billion: Increase in drug expenditures due to the elimination of cost-sharing for currently-insured persons** (17% of the $345.6 billion in estimated prescription drug expenditures by and on behalf of this group, with 10% of the increase offset by savings on non-drug expenditures).

### New costs for public R&D

$39.0 billion: NIH Clinical Trials Division[i] (funding for 90% of clinical trials)

$21.7 billion: NIH Drug Innovation Division[j] (funding of half of current pre-clinical private R&D)

**$ 60.7 billion: New Public R&D costs[k]**

### New regulatory agency costs

$1.2 billion: Replacement of FDA Drug User Fees[l]

$1.8 billion: Bolstered postmarket drug safety monitoring[m]

$0.2 billion: Expanded FDA promotional monitoring[n]

**$3.2 billion: New regulatory costs**

### Net savings and costs

$ 154.6 billion: Overall savings

$ 139.5 billion: Overall new costs

**$15.1 billion: Estimated net savings, 2017°**

* Methods, sources and assumptions are described in a separate methodology document. Figures in this table may not add up due to rounding.

VA = US Veterans Health Administration
R&D = research and development
NIH = National Institutes of Health
FDA = US Food and Drug Administration

## Methodology for Table 7

[a] The figures for national drug expenditures (total and by payer) are CMS's 2017 National Health Expenditure (NHE) estimates.[46]

[b] The NHE estimates of drug spending are for retail drug spending only; spending for drugs administered by hospitals or physicians are included in the expenditure estimates for those providers. Hence, to calculate total (retail + non-retail) drug spending using the NHE retail drug spending estimates, we followed the approach of the Department of Health and Human Services, which estimates that non-retail drug spending constitutes 28% of total drug spending.[47]

[c] Given that many public payers (e.g. Medicaid and the VA, but not Medicare) already obtain significantly discounted drug prices, we excluded these payers from our calculation of potential savings. However, our non-retail drug spending estimate is calculated as indicated in note b above (i.e. 28% of total drug spending), and is not disaggregated by payer. Thus, in order to estimate total drug spending by non-discounted payers, we assumed that the percent of retail drug spending by discounted payers in the NHE (14% of total retail spending) also applied to total drug spending.

[d] This percentage is from Kesselheim et al.[48] A similar estimate (74.2%) is provided by the IQVIA Institute for Human Data Science based on invoice drug prices for 2016.[49] (p. 45)

[e] We estimate that drug prices could be reduced by approximately 50% based on international price comparisons from several sources. For instance, Squires reports Gerard Anderson's analysis of IMS health data (exhibit 6)[50] on the average prices paid for the 30 most commonly prescribed drugs in the US and 8 other OECD nations (Australia, Canada, France, Germany, Netherlands, New Zealand, Switzerland, and the United Kingdom). Overall, the ratio of median drug prices in these 9 nations to the median price in the US was 0.51 (including both generic and brand-name agents), consistent with our assumption that the US could cut drug prices in half.

A more recent report from Gagnon and Wolfe, also relying on IMS data, examined 640 brand-name drugs and utilized US sales-weighted averages, provides a similar estimate. Gagnon and Wolfe found that in 2014, OECD median average drugs prices were 42% those of the US, and asserted that "one can safely conclude that Medicare Part D … pays at least twice as much as the OECD median for patented drugs."[51]

Others analyses of comparative prices using different approaches support the view that US drug prices are significantly higher than other high-income nations'. For instance, Kanavos et al., also using IMS data, estimated drug "price indices" weighted for consumption patterns for the US, the UK, Switzerland, Germany, France, Canada, and Australia.[52] Depending on the comparator nation, whether the analysis examined retail or manufacturing prices, and whether US or nation-specific weighting was utilized, they found that US drug prices were between 5% and 198% higher than other nations'. Their analysis based on retail drug prices using US weights found that as compared to a price index of 100 for the US, the index was 49 in Australia, 50 in Canada, 61 in France, 95 in Germany, 88 in Switzerland, and 46 in the UK.

Overall, our estimate of a 50% reduction in drug prices with drug negotiations is consistent with the prices in nations that most effectively lowered drug prices in this study.

Finally, our estimate is supported by the lower prices paid by the US Veterans Health Administration (VA), which negotiates for drug prices and maintains a formulary. A dated estimate from the Congressional Budget Office puts prices paid by the VA for branded drugs at 42% of the average wholesale price.[53] Frakt et al., drawing on four studies, assert that the VA obtains drug prices approximately 60% of those paid by Medicare.[54] Together, these estimates accord with our estimate of an approximately 50% reduction in drug prices through negotiations and a formulary.

As noted, we do not apply this 50% reduction to Medicaid or other federal health programs which currently receive substantial discounts (including the VA, but not Medicare). It seems likely that the prices paid by these programs would also be reduced, albeit to a lesser extent.

An alternative approach to computing likely savings (which some have adopted[55]) would rely on differences in national per-capita drug spending. For instance, an assumption that the United States could reduce its overall per-capita drug spending to the OECD average (approximately half that in the US) would project substantially larger savings than those we estimated. However, this approach does not take into account differences in the quantity of drugs consumed. Hence, we elected to conservatively estimate savings based on price differences.

[f] The figure for the number of uninsured is CBO's 2017 projection.[56]

[g] This figure is based on a study of Mulcahy et al examining the impact of the ACA on drug spending for previously uninsured individuals.[57] This figure accounts only for new program spending, and does not incorporate reductions in out-of-pocket payments. To be conservative, we used the higher of the two figures reported by Mulcahy et al, an estimate based on individuals newly covered by Medicaid, which carries low or no cost-sharing for medications.

[h] We rely here on the estimate of overall "relative spending" from

Choudhry et al., whose randomized trial evaluated the effect of eliminating copayments for drugs in patients who have suffered a myocardial infarction, which most closely resembles the policy change we envision. In that study, although eliminating cost-sharing for medications increased medication spending, it did not increase total healthcare spending because it was completely offset by savings on non-drug expenditures.[58] However, we conservatively estimated that only 10% of the added expenditures for drugs would be offset by reduced non-drug spending.

We apply the estimated 17% increase in drug spending from eliminating cost-sharing to our estimate of total drug spending after adjustment for a 50% reduction in brand-name drug prices for non-discounted payers (i.e. total current estimated 2017 drug spending of $500.1 billion minus estimated savings of $154.6 billion). Since this includes spending on inpatient drugs (the utilization of which would likely be less affected by the elimination of cost-sharing), our spending estimate likely overstates the cost of eliminating cost-sharing.

[i] This figure is based on estimates by PhRMA,[59] the pharmaceutical industry lobbying group, and D. Baker.[55]

PhRMA reported that R&D spending for the entire U.S pharmaceutical industry totaled $67.4 billion in 2010, of which $50.7 billion was spent by PhRMA member companies. For more recent years, PhRMA only provides estimates for PhRMA member firms' spending, which in 2015 totaled $58.8 billion.[59] We assumed that the ratio of PhRMA member company R&D spending to overall industry R&D spending in 2010 (75.2%) remained the same in 2015. Thus, for 2015, we estimate $78.17 billion in total industry R&D spending. In order to inflate this figure to 2017, we assumed that R&D spending rose at the same rate as total outpatient prescription drug spending (11% between 2015 and 2017).[46] Thus, for 2017 we estimate approximately $86.7 billion in total private sector R&D in 2017.

We follow Baker in assuming that approximately half of industry drug development spending is preclinical and half clinical.[55] Applying this ratio to the 2017 R&D estimate of $86.7 billion suggests that about $43.4 billion will be spent on clinical testing in 2017. Under the assumption that 90% of clinical trials would be publicly funded, we estimate that $39.0 billion in funding would be required to support public clinical trials.

[j] As noted above, we assume that approximately half of preclinical drug development will be publicly funded, i.e. 25% (50% of 50%) of the total R&D figure of $86.7 billion, or $21.7 billion.

[k] Chakravarthy et al. estimate that NIH spending would have to roughly increase 2.5 fold to replace total private sector R&D.[60] Since the 2016 NIH budget totaled $31.3 billion, this translates into an approximate total NIH budget of $78.3 billion, or an increase of $47.0 billion. We have projected a considerably higher estimate, a $61.6 billion increase in NIH funding. However, our figure was meant to only cover 90% of clinical trials and 50% of basic science research (not 100% of the cost of both components, the basis for Chakravarthy et al's figure). Thus, our estimate of added spending for public sector drug development may overstate costs; a lower sum may suffice.

[l] For 2017, the FDA was projected to receive a total of $1.2 billion in human drug-related user fees: $866 million for prescription drugs (PDUFA), $324 million for generic drugs (GDUFA), and $22 million for biosimilars (BSUFA).[61]

[m] FDA spending for human drug and biologic programs totaled $1.768 billion in 2017 ($1,408 million and $360 million, respectively). The vast majority of these funds currently go towards drug approval activities. Hence, we estimate that an additional $1.8 billion would be required to bring funding for post-marketing surveillance activities on a par with the funding for drug approval activities.[61]

[n] In 2015, FDA spending on "Drug Marketing, Advertising, and Communication Activities" was $17.127 million.[62] An approximately ten-fold increase in this figure, rounded to one decimal point in billions, yields our figure of $0.2 billion.

[o] Overall, this estimate is likely conservative. For instance, it excludes longer-term savings from patent reform, improved prescribing resulting from drug promotion reform, and increasing the share of drugs in the public domain through the new "public track" programs.