

## Impact of Race on Classification of Atherosclerotic Risk Using a National Cardiovascular Risk Prediction Tool



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**Introduction:** The use of race in clinical risk prediction tools may exacerbate racial disparities in healthcare access and outcomes. This study quantified the number of individuals reclassified for primary prevention of cardiovascular disease owing to a change in their race alone on the basis of a commonly used risk prediction tool.

**Methods:** This is a cross-sectional analysis of individuals aged 40–75 years without a history of cardiovascular events, diabetes, or other high-risk features using the 2005–2018 National Health and Nutritional Examination Survey. Authors compared atherosclerotic cardiovascular disease risk scores using the American Heart Association/American College of Cardiology equation recommended for White individuals or individuals of other races with that recommended for Black individuals.

**Results:** A total of 2,946 White individuals; 1,361 Black individuals; and 2,495 individuals of other races were included in the analysis. Using the American Heart Association/American College of Cardiology equation, the mean 10-year atherosclerotic cardiovascular disease risk was 5.80% (95% CI=5.54, 6.06) for White individuals, 7.04% (95% CI=6.69, 7.39) for Black individuals, and 4.93% (95% CI=4.61, 5.24) for individuals of other races. When using the American Heart Association/American College of Cardiology equation designated for the opposite race (White/other race versus Black), the mean atherosclerotic cardiovascular disease risk score increased by 1.02% (95% CI=0.90, 1.13) for White individuals, decreased by 1.82% (95% CI= -1.67, -1.96) for Black individuals, and increased by 0.98% (95% CI=0.85, 1.10) for individuals of other races. When using clinical atherosclerotic cardiovascular disease categories of <7.5%, 7.5%–10%, and >10%, 16.93% of all individuals were reclassified when using the American Heart Association/American College of Cardiology's equation designated for the opposite race.

**Conclusions:** Changing race within a commonly used cardiovascular risk prediction tool results in significant changes in risk classification among eligible White and Black individuals in the U.S.

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## INTRODUCTION

The clinical value and propriety of using race in predictive algorithms has recently come into question, in part owing to growing evidence that such use may perpetuate racial disparities in processes or outcomes of care.<sup>1,2</sup> For example, the equation for glomerular filtration rate along with the algorithm to predict a successful vaginal birth after cesarean section have both recently been modified to exclude race.<sup>3,4</sup> Pulmonary function testing in the U.S. also typically utilizes race when assessing lung disease, and there has been a push toward using race-composite reference standards to prevent potential bias.<sup>5</sup>

The atherosclerotic cardiovascular disease (ASCVD) risk score is a commonly used prediction tool recommended for decision making on cholesterol-lowering medication, aspirin use, hypertension management goals, and use of diagnostics such as coronary calcium scoring. The most recommended algorithm for calculating an individual's ASCVD is the American Heart Association and American College of Cardiology (AHA/ACC) pooled cohort equations, a set of 4 equations used to predict an individual's 10-year risk of a cardiovascular event.<sup>6</sup> These 4 equations are separated by biological sex (male or female) and race (non-Hispanic White or non-Hispanic Black). Individuals who identify as neither White nor Black are recommended to use the equation for non-Hispanic Whites. These 4 equations differ in the weights assigned to each biological risk factor used in the calculation of an individual's ASCVD risk scores. Consequently, 2 individuals may have identical clinical risk factors but different ASCVD risk scores because of their race or sex alone. Vasani and van den Heuvel<sup>7</sup> recently showed that these variations in weights can lead to substantially different ASCVD risk estimates for Black versus White individuals who have identical risk profiles. It is currently unclear how many individuals, especially those who identify as Black, would have a clinically significant change in their ASCVD score if only they used the AHA/ACC equation of the opposite race.

The race-agnostic 2008 Framingham Risk Score (FRS)<sup>8</sup> has also been used to calculate the 10-year risk of a cardiovascular event and may be a potential option for physicians and patients who prefer an equation that does not include race. Although there has been concern about FRS's predictive ability in non-White populations, Fox et al.<sup>9</sup> showed that the FRS performed similarly to the AHA/ACC equation when applied to the largely African American Jackson Heart Study Cohort.<sup>9–12</sup> To our knowledge, no studies have estimated the population-level impact of switching to the race-agnostic FRS from the widely used AHA/ACC equation.

We used a nationally representative survey to examine the proportion of individuals who would have clinically significant shifts in their estimated ASCVD risk if they used the AHA/ACC equation of the opposite race (White/other race versus Black), keeping all other risk factors constant. In addition to characterizing the sensitivity of the AHA/ACC equations to race, we also compared the potential impact on ASCVD when switching individuals to the race-agnostic FRS.

## METHODS

### Study Sample

National Health and Nutritional Examination Survey (NHANES) is a nationally representative survey that uses stratified multistage probability-cluster sampling to make inferences about the health of the U.S. population. The survey is conducted every 2 years with participants from selected counties across the U.S. Participants complete an interview that includes demographic, socioeconomic, and health-related questions. A smaller subset completes a medical examination component that includes vital signs, serum testing for cholesterol and diabetes, and other measurements. The data, along with guidance on its design and interpretation, are available through the National Center of Health Statistics.<sup>13</sup>

The authors conducted a cross-sectional analysis of participants in the 2005–2018 NHANES. Authors used seven 2-year data sets, encompassing 14 years of data, to account for the smaller sample of eligible populations within 1 survey cycle. They omitted data from the 2019–2020 NHANES owing to a decrease in the number of clinical examinations during the coronavirus disease 2019 (COVID-19) pandemic. They used the assigned survey weights corresponding to the individuals receiving a medical examination and generated a composite weight for the 7 combined 2-year datasets per the Centers for Disease Control and Prevention's analytic guidance.<sup>14</sup>

Authors focused on individuals aged between 40 and 75 years given the applicability of the AHA/ACC equation to this age group and current U.S. Preventive Services Task Force (USPSTF) recommendations using this threshold.<sup>15,16</sup> Individuals with a self-reported history of diabetes, a fasting blood sugar >140, a low-density lipoprotein >190, or a prior cardiovascular event were excluded given that these individuals would already be eligible for cholesterol-lowering medications. Eligible individuals who did not have information regarding important covariates of interest such as blood pressure or total cholesterol were also excluded.

**Statistical Analysis**

Authors used data from the NHANES interviews and clinical and laboratory examinations to derive the risk factors used in the AHA/ACC equations and FRS. These variables included age (years), race (White, Black, other), systolic blood pressure (mm Hg), diabetes (yes/no), current smoking history (yes/no), total cholesterol (mg/dL), high-density lipoprotein (mg/dL), and whether they are currently treated for hypertension (yes/no). An individual’s blood pressure was calculated from a mean of 3 ambulatory blood pressures taken during a patient’s examination, in alignment with previous methods for calculating ASCVD from NHANES.<sup>17</sup> Cholesterol levels were extracted from the patient’s laboratory data, and diabetes status was assigned on the basis of self-report or if fasting glucose was >140 mg/dL. Finally, authors used interview data to derive information on smoking status and use of hypertension medications.

Authors calculated 3 ASCVD risk scores for each individual: one using the AHA/ACC equation designated for non-Hispanic White and individuals of other races, one using the AHA/ACC equation for non-Hispanic Black individuals, and one using the race-agnostic FRS. Individuals who did not identify as non-Hispanic White or non-Hispanic Black used the AHA/ACC equation designated for White individuals. These individuals were then separated into 3 racial groups on the basis of their initially reported race: non-Hispanic White, non-Hispanic Black, and other. Individuals who identified as having Hispanic ethnicity, in addition to all other racial groups, were categorized as other.

Authors further categorized individuals into 3 clinically significant ASCVD groups of <7.5%, 7.5%–10%, and >10% for each risk equation, corresponding to the 10-year risk of a cardiovascular event. These thresholds were selected on the basis of thresholds used in current

recommendations from the USPSTF and the AHA/ACC for determining primary prevention of cardiovascular disease.<sup>18,19</sup> For example, the USPSTF recommends cholesterol-lowering medications for eligible individuals with a score >10%.

Using examination survey weights provided in NHANES, authors calculated the mean ASCVD scores for each racial group using the 3 risk equations. The mean difference between each score was then calculated. To determine the clinical significance of switching between scores, authors then summed the total number of individuals within each race who shifted risk groups when using either the equation of the opposite race or the race-neutral FRS. National estimates were then calculated as percentages using established examination survey weights.

This analysis was exempt from a Johns Hopkins Bloomberg School of Public Health IRB because it did not constitute human subject research. All individuals participating in NHANES provided written consent. All analyses were conducted using Stata software, Version 17.0 (StataCorp).

**RESULTS**

A total of 22,170 individuals aged between 40 and 75 years were included in the 2005–2018 NHANES. Of these, 12,986 (25.82%) who did not have relevant examination or laboratory data; 810 (3.7%) individuals with a history of a cardiovascular event; 1,320 (6.0%) owing to a history of diabetes; and 252 (1.1%) with low-density lipoprotein >190 were excluded, leaving 6,802 individuals in the final analysis. Of these, 2,946 (43.3%) identified as non-Hispanic White; 1,361 (20.0%) identified as non-Hispanic Black; and 2,495 (36.7%) identified as a race other than non-Hispanic White or Black (Table 1).

**Table 1.** Prevalence of Risk Factors Among Study Population Stratified by Race

Risk factors	Race					
	Non-Hispanic White n = 2,946		Non-Hispanic Black n = 1,361		Other n = 2,495	
Age at screening, years, mean ±SD	56.1	±10.3	55.0	±9.4	54.6	±9.7
Gender						
Female, n (%)	1,497	(50.8%)	704	(51.7%)	1,332	(53.4%)
Current smoker						
Yes, n (%)	405	(13.7%)	213	(15.7%)	200	(8.0%)
Treated hypertension						
Yes, n (%)	969	(32.9%)	628	(46.1%)	669	(26.8%)
Mean systolic blood pressure, mm/hg ±SD	122.5	±16.6	130.5	±19.5	124.4	±17.5
Total cholesterol, mg/dL ±SD	199.5	±35.3	193.9	±36.1	200.6	±34.5
Direct HDL cholesterol, mg/dL ±SD	56.5	17.6	59.2	18.3	53.9	15.1

HDL, high-density lipoprotein.

**Table 2.** Mean Atherosclerotic Cardiovascular Disease Scores With Mean Difference by Race and Equation

ASCVD risk equation	Race Mean difference (95% CI)					
	Non-Hispanic White		Non-Hispanic Black		Other	
Pooled cohort equations						
White equation	5.80	(5.54, 6.06)	5.23	(4.91, 5.54)	4.93	(4.61, 5.24)
Black equation	6.81	(6.55, 7.08)	7.04	(6.69, 7.39)	5.91	(5.62, 6.19)
Difference	1.02	(0.90, 1.13)	-1.82	(-1.67, -1.96)	0.98	(0.85, 1.10)
Framingham						
Mean	9.50	(9.18, 9.81)	9.68	(9.26, 10.10)	8.91	(8.49, 9.33)
Difference <sup>a</sup>	3.70	(3.57, 3.83)	2.64	(2.45, 2.82)	3.98	(3.81, 4.16)

<sup>a</sup>Framingham difference = Framingham Risk Score – assigned race pooled cohort equation.

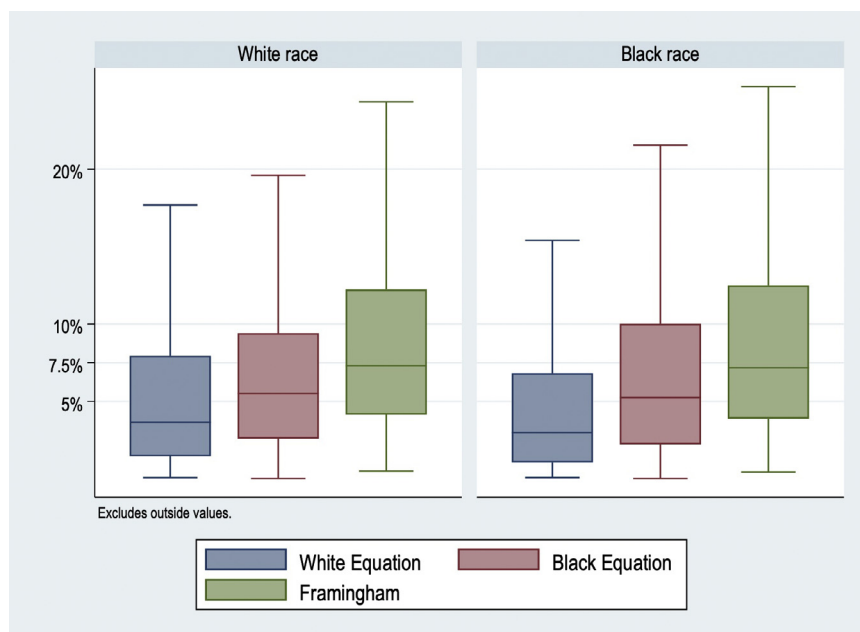
In the study sample, the mean ASCVD risk score for non-Hispanic Whites using the White AHA/ACC equation was 5.80% (95% CI=5.54, 6.06) (Table 2). The mean risk score for non-Hispanic Black individuals using the Black AHA/ACC equation was 7.04% (95% CI=6.69, 7.39). For individuals who identify as a race other than White or Black, their mean ASCVD risk score using the recommended White AHA/ACC equation was 4.93% (95% CI=4.61, 5.24).

The mean difference in ASCVD risk score when switching from the White AHA/ACC equation to the Black AHA/ACC equation was +1.02% (95% CI=0.90, 1.13) for White individuals and +0.98% (95% CI=0.85, 1.10) for individuals of races other than White or Black (Figure 1). The mean difference for Black individuals

when switching to the White AHA/ACC equation was -1.82% (95% CI= -1.67, -1.96).

When comparing shifts in clinically significant categories (<7.5%, 7.5%–10%, or >10%), 16.93% of all eligible individuals switched to a different risk category when using the opposite race equation (Figure 2). A total of 10.92% of White individuals crossed the threshold of 7.5%, with the majority (9.59%) being reclassified above 7.5% when switching to the Black AHA/ACC equation (Table 3). A total of 8.99% of White individuals crossed the 10% threshold, with the majority (6.60%) being reclassified higher to above 10% (Table 3).

For Black individuals, 13.10% crossed the threshold of 7.5% ASCVD when switching to the White AHA/ACC



**Figure 1.** ASCVD risk estimates by race and equation. ASCVD, atherosclerotic cardiovascular disease.

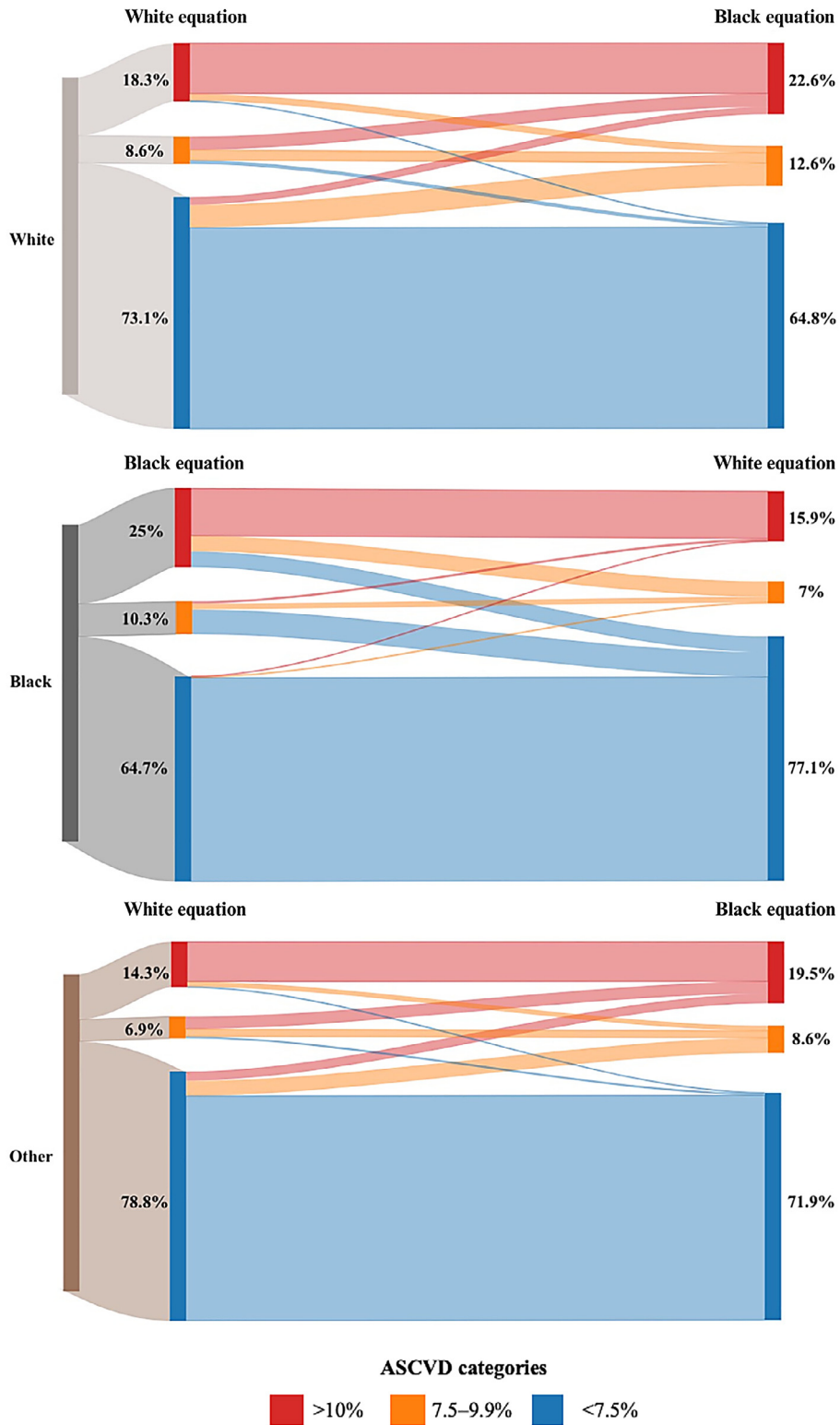


Figure 2. Percentage of risk reclassification by race.



**Table 3.** Proportion of Individuals With Reclassified ASCVD Due to Race Change Only

Change in ASCVD risk	Race		
	Non-Hispanic White n=2,946	Non-Hispanic Black n=1,361	Other n=2,495
10-year ASCVD risk of 7.5%			
No change in classification	89.08%	86.90%	91.43%
Increased risk (from <7.5% to >7.5%)	9.59%	0.34%	7.73%
Decreased risk (from >7.5% to <7.5%)	1.34%	12.75%	0.85%
10-year ASCVD risk of 10.0%			
No change	91.01%	89.27%	91.42%
Increased risk (from <10% to >10%)	6.60%	0.81%	6.88%
Decreased risk (from >10% to <10%)	2.39%	9.92%	1.70%

ASCVD, atherosclerotic cardiovascular disease.

equation. The majority were reclassified lower (12.75%). A total of 10.73% crossed the 10% threshold when their race was switched, with the majority (9.92%) being reclassified lower.

For individuals who identify as a race other than White or Black, a total of 8.58% crossed the threshold of 7.5%, with again the majority being an upward reclassification (7.73%). A total of 8.58% also crossed the threshold of 10%, with 6.88% being reclassified higher.

The mean risk score for White individuals using the FRS was 9.50% (95% CI=9.18, 9.81). The mean risk score for non-Hispanic Black individuals using the FRS was 9.68% (95% CI=9.26, 10.10). For individuals who identify as a race other than White or Black, the mean ASCVD was 8.91% (95% CI=8.49, 9.33). When comparing the ASCVD risk score from the AHA/ACC equation for an individual assigned race with score from the race-neutral FRS, all race groups had an increase in risk, with a mean difference of +3.70% absolute change for White, +2.64% for Black, and +3.98% for individuals of other races.

## DISCUSSION

The use of race in clinical risk prediction tools may exacerbate racial disparities in healthcare access and clinical outcomes. This study quantified the impact of race on estimated 10-year cardiovascular risk on the basis of a widely used cardiovascular risk prediction tool. On average, White and other non-Black individuals had higher risk scores when using the Black AHA/ACC equation, whereas Black individuals had lower scores when using the White AHA/ACC equation. All races on average had higher ASCVD scores when switched to the race-agnostic FRS. Although the mean shift in risk appears small, approximately 17% of eligible individuals were

reclassified into a different risk group when using the opposite race-based AHA/ACC equation. These differences have large clinical implications, such as the roughly 10% of Black individuals who would no longer be recommended for statin therapy if they used the White AHA/ACC equation.

Clinicians in the U.S. often rely on ASCVD risk score categorization when making decisions on primary prevention using cholesterol-lowering medication or aspirin, deciding on hypertension management goals, and pursuing further risk assessment with diagnostics such as coronary calcium scoring.<sup>19</sup> Although it has been widely shown that the AHA/ACC equations can overestimate ASCVD risk, less is known regarding the clinical implications of such overestimation.<sup>20–22</sup> This study was not designed to show whether the AHA/ACC's risk equations overestimate risk in different racial groups because this would require assessment of patient outcomes. Instead, the analyses reveal how subtle differences between the White and Black AHA/ACC equations lead to large population-level shifts in risk groupings only on the basis of race, a situation that may perpetuate disparities through differential diagnosis or treatment.

The optimal use of race in clinical risk prediction algorithms remains an important area of investigation. The U.S. is rare in its use of race in cardiovascular risk assessment, with most high-income countries using only traditional biological risk factors.<sup>23</sup> Although cardiovascular disease is misdiagnosed in all ethnicities, there are large and persistent racial and ethnic disparities in cardiovascular disease that are multifactorial in origin. Evidence suggests that these racial differences can be explained in part by social determinants of health such as economic status, parental education, and even neighborhood (possibly mediated through health-promoting amenities or environmental factors).<sup>24,25</sup>

Despite this growing evidence that racial disparities are secondary to socioeconomic differences, the AHA/ACC equations use only biological variables. Instead of a single variable for race, as is typically seen in race-based algorithms, the AHA/ACC equations use separate variable weights for White and Black individuals. This difference in weighting, such that smoking has a higher impact on cardiovascular risk for White women than for Black, implies a biologic difference in the pathophysiology of cardiovascular disease between races. The most recent recommendation from the USPSTF on statin use addresses this contradiction, stating that race is a social construct and that clinicians should use the AHA/ACC equation risk score only as an estimate.<sup>18</sup>

Although the race-agnostic FRS avoids the complexities of race-based prediction algorithms, this study's data show that a national switch would result in a large transition of individuals into higher-risk categories than currently classified using the AHA/ACC's pooled risk equations. In the pursuit of a race-neutral equation, it is likely that a new threshold or equation would be required to avoid large overestimations of risk. Modern cohorts containing more complex socioeconomic factors could help understand upstream causes of racial disparities, although their use in clinical prediction algorithms would likely prove difficult.<sup>21</sup>

### Limitations

This study had several limitations. First, the authors calculated the population health impact of race using the AHA/ACC equation and FRS, but they did not attempt to assess the predictive accuracy of each equation within racial groups. Second, the analysis relied upon NHANES interview data to assess risk factors such as smoking and current treatment, and differential misclassification of these by race could affect the conclusions. Third, the number of individuals participating in NHANES was relatively small, introducing uncertainty into the estimates.

### CONCLUSIONS

In summary, a significant number of individuals in the U.S. would have a meaningful change in their ASCVD risk class if their race alone was changed when using the AHA/ACC's equation. Use of the race-agnostic FRS would result in a large shift in risk class for individuals of all races. A new race-agnostic risk equation could improve estimations using more modern cohort data and including factors associated with racial disparities in ASCVD.

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### DECLARATION OF INTEREST

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: G. Caleb Alexander reports a relationship with FDA's Peripheral and Central Nervous System Advisory Committee that includes: consulting or advisory. G. Caleb Alexander reports a relationship with Monument Analytics that includes: equity or stocks. Dr. Alexander is past Chair and a current member of FDA's Peripheral and Central Nervous System Advisory Committee; is a co-founding Principal and equity holder in Monument Analytics, a health care consultancy whose clients include the life sciences industry as well as plaintiffs in opioid litigation, for whom he has served as a paid expert witness; and is a past member of OptumRx's National P&T Committee. These arrangements have been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies.

### CREDIT AUTHOR STATEMENT

Jarett R. Beaudoin: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Validation, Visualization, Writing – original draft. Jill Curran: Project administration, Writing – review & editing. G. Caleb Alexander: Conceptualization, Investigation, Supervision, Writing – review & editing.

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