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Diagnostics' New Supreme Court Risk

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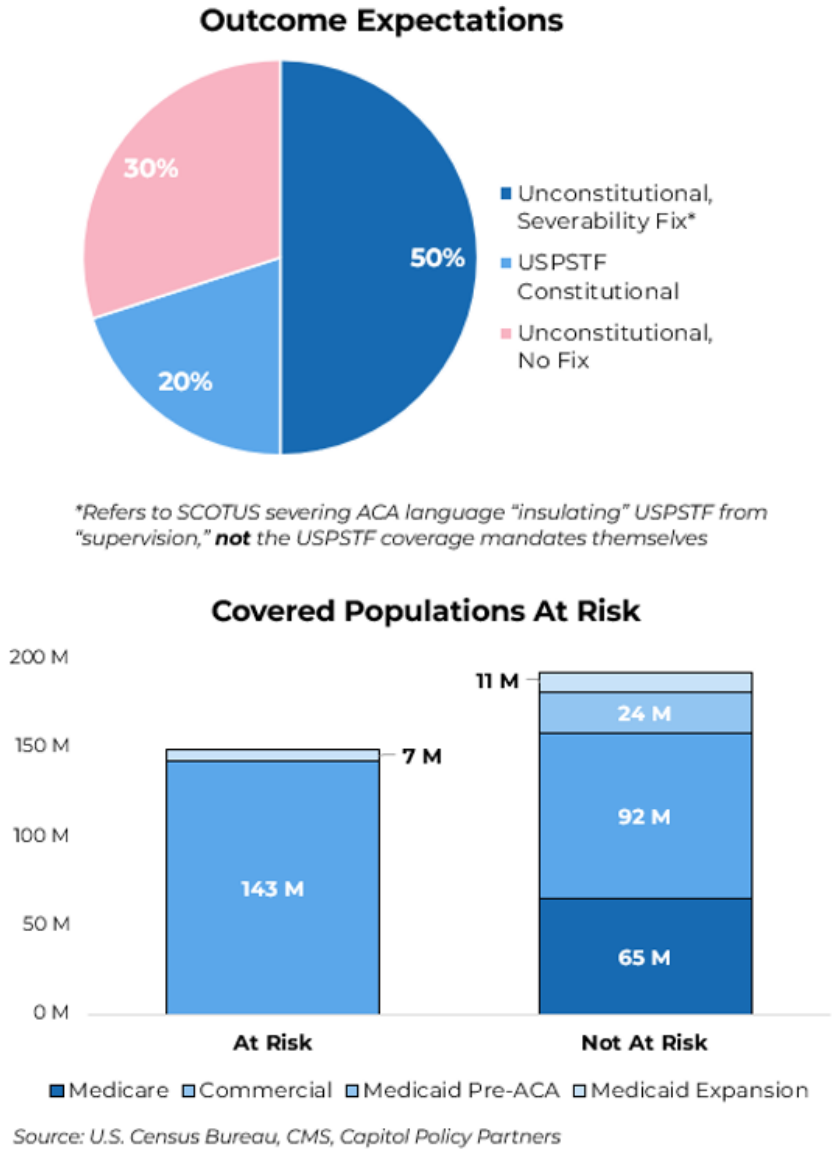
The Supreme Court's (SCOTUS) decision on Friday to hear oral arguments in *Becerra v. Braidwood*, presumably in late March / early April, will likely serve as an overhang for screening test manufacturers [**EXAS, GH, MYGN, NEO, HOLX, OSUR**] until a decision is handed down in late June, but we ultimately think current policy supporting demand for these companies' products endures. Recall that the lawsuit challenges the Affordable Care Act's (ACA) requirement that insurers cover services with Grade A / B recommendations from the U.S. Preventive Services Task Force (USPSTF) with zero out-of-pocket (OOP) costs, which we estimate as applicable to ~150M people.



EXACT Sciences Corporation (EXAS)

Price:	$56.50
52-Week High:	$79.62
52-Week Low:	$40.62

Guardant Health Inc (GH)

Price:	$36.70
52-Week High:	$38.53
52-Week Low:	$15.81

Myriad Genetics Inc (MYGN)

Price:	$14.83
52-Week High:	$29.30
52-Week Low:	$12.87

Hologic Inc (HOLX)

Price:	$71.70
52-Week High:	$84.67
52-Week Low:	$70.36

NeoGenomics Inc (NEO)

Price:	$14.77
52-Week High:	$19.12
52-Week Low:	$12.77

OraSure Technologies Inc (OSUR)

Price:	$3.62
52-Week High:	$8.33
52-Week Low:	$3.52

Quick Refresh: What SCOTUS is Weighing?

This case is about whether the USPSTF's recommendations are legal given that its members and activities are "insulated" from political supervision by statute.

It is ***not*** about whether the government has authority to mandate insurance coverage based on the recommendations of a given advisory body, which the lower courts in this case even endorsed as it relates to vaccines from the Advisory Committee on Immunization Practices (ACIP) and preventive care guidelines for children from the Health Resources & Services Administration (HRSA).

Whereas both ACIP and HRSA operate "under the supervision and direction" of the HHS Secretary, the ACA stipulates that "[a]ll members of the USPSTF…and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure."

With their recommendations constituting binding policy, however, without a need for formal ratification by HHS, two lower courts have found that this construct violates the Constitution, and the Biden administration now asks SCOTUS to decide the following:

1. Are USPSTF members operating as "principal officers" of the United States, in violation of the Constitution's Appointments Clause requiring Senate confirmation?
2. Does the HHS Secretary's ability to remove Task Force members at will instead render them "inferior officers," and thus "under the supervision and direction" of a "principal officer"?
3. If USPSTF members *are* in fact operating as "principal officers," would severing the ACA provision "insulating" them from political oversight solve the constitutional defect, allowing the HHS Secretary to ratify Task Force recommendations, as it did in June 2023?

USPSTF Grade A & B Screening Recommendations

YEAR	SCREENING TESTS	GRADE	COMPANIES
2024	Breast Cancer	B, I	MYGN, NEO, HOLX, GEHC
2021	Colorectal Cancer	A, B, C	EXAS, GH
2021	Lung Cancer	B, I	BDSX, ROG.SW, VCYT, SHL.GY
2019	BRCA-Related Cancer	B, D	MYGN, NEO, FLGT, WGS, DGX, LH
2019	HIV Infection	A, B, C	ABT, OSUR
2018*	Cervical Cancer	A, D	HOLX, BDX, DHR. ROG.SW

** Update in progress*

Source: USPSTF, Capitol Policy Partners

Where Will SCOTUS Land?

We suspect that the nature of these questions allows the Court to rule in a way that allows the basic structure of existing coverage mandates to stand, while also appealing to both the anti-ACA instincts of some conservatives *and* Chief Justice John Roberts / Justice Brett Kavanaugh's traditional hesitation to subvert the expressed will of Congress.

Despite the fact that the ACA lacks an explicit severability clause, a majority of the justices have previously presumed that Congress did not intend the validity of the statute in question to depend on the validity of a constitutionally offensive provision.

In other words:

- We would expect SCOTUS to determine that the ACA's "insulating" language renders Task Force operations unconstitutional; ***but***
- What Chief Justice Roberts has called the "settled severability doctrine" allows for the severing of this offending provision, allowing USPSTF coverage mandates to continue under the same authorities as those from ACIP and HRSA.

Justice Kavanaugh has previously argued this point as well, referring to the Court's "decisive preference for surgical severance rather than wholesale destruction, even in the absence of a severability clause."

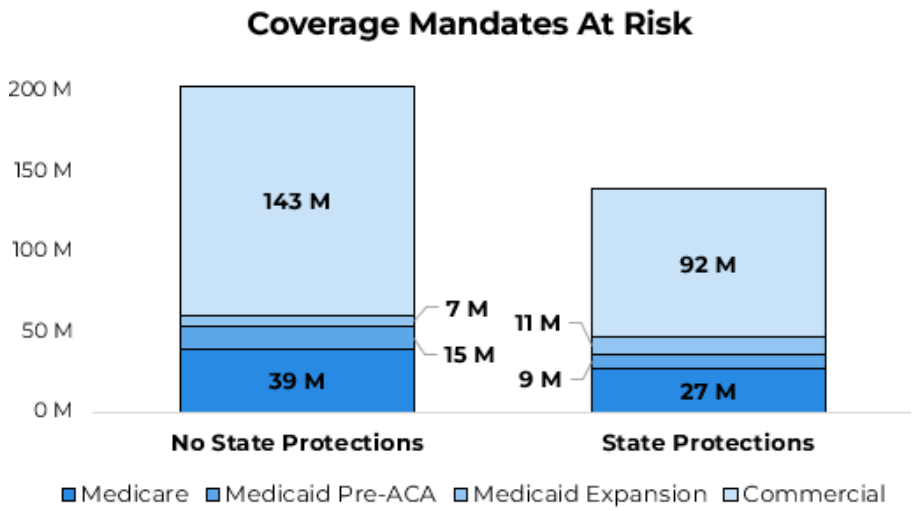
For those keeping score at home, the support of Roberts and Kavanaugh, combined with the Court's three Democratic appointments, would result in a 5-4 decision preserving USPSTF coverage mandates, with Justice Amy Comey Barrett being a potential swing vote as well.

While our outcome expectations above actually list a broad finding of constitutionality as the *least* likely outcome (20%), its combination with the prospects for a severability fix (50%) results in our subjective 70% odds for current policy to be maintained.

What If We're Wrong: Impact on Coverage

Note that the ACA's USPSTF mandates apply to insurance coverage in the individual, group, and employer markets, as well as the expanded Medicaid populations in the 40 states + DC that have elected to do so. The requirement does *not* apply to Medicare fee-for-service (FFS), Medicare Advantage (MA), or pre-ACA Medicaid populations. Similarly, we count 17 states + DC that have codified their own preventive service mandates mirroring ACA standards. In other words, we view this case as largely non-applicable to 56% of the population.

That said, this still leaves ~150M (44%) that have commercial insurance (~143M) or are part of the Medicaid expansion population (~7M) in states that have not adopted unilateral coverage mandates, representing ~60% and ~40% of those groups, respectively.



Source: U.S. Census Bureau, CMS, Capitol Policy Partners

We nevertheless think it improbable that payers would eliminate preventive screening coverage for roughly half the population, as suggested by America's Health Insurance Plans (AHIP) – the national insurance lobby – in the immediate

aftermath of the original district court ruling against the USPSTF mandate in March 2023:

"Every American deserves access to…preventive care and services that help avoid illnesses and other health problems. As we review the decision and its potential impact with regard to the preventive services recommended by the USPSTF, we want to be clear: Americans should have peace of mind there will be no immediate disruption in care or coverage."

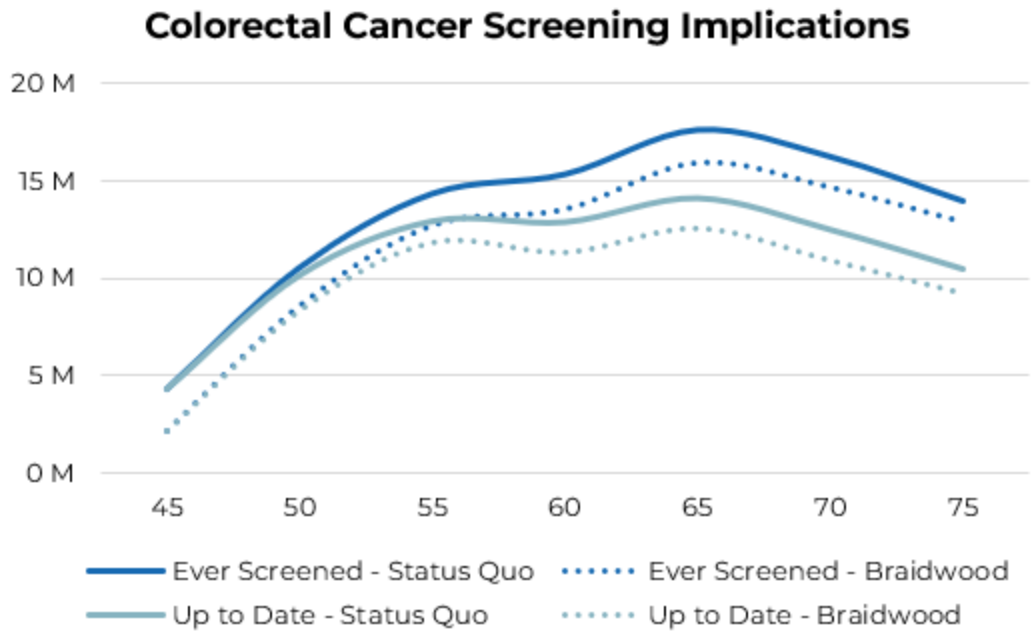
A more likely approach would therefore be to institute patient cost-sharing in future plan years, pressuring volumes. Without a mandate in place that *requires* coverage, we would also expect a concomitant loss of leverage for test manufacturers in reimbursement negotiations, eroding margins.

What If We're Wrong: Impact on Colorectal Cancer (CRC) Screening

- ***Estimates suggest ~13% decline in utilization***

Acknowledging the inherent uncertainties involved in such projections, we sought to extrapolate findings from the NIH Cancer Intervention & Surveillance Modeling Network (CISNET), which in Oct. 2024 specifically sought to quantify the potential impact of an adverse ruling in this case on CRC screening participation.

While the NIH study focuses only on colonoscopy and fecal immunochemical testing (FIT), rather than the stool DNA [EXAS] or blood-based biomarker [GH] approaches, its sensitivity analyses imply a long-term decline in screening participation by an aggregate 11M (13%) for those up to the age of 75.



CISNET EXTRAPOLATIONS	45	50	55	60	65	70	75	TOTAL
Ever Screened - Status Quo	4.4 M	10.6 M	14.3 M	15.3 M	17.6 M	16.2 M	14.0 M	***92 M***
Ever Screened - Braidwood	2.2 M	8.6 M	12.7 M	13.6 M	16.0 M	14.7 M	12.9 M	***81 M***
#Δ	***-2.2 M***	***-1.9 M***	***-1.6 M***	***-1.8 M***	***-1.6 M***	***-1.5 M***	***-1.0 M***	***-12 M***
%Δ	***-50%***	***-18%***	***-11%***	***-11%***	***-9%***	***-9%***	***-7%***	***-13%***
Up to Date - Status Quo	4.4 M	10.2 M	12.9 M	12.9 M	14.1 M	12.5 M	10.5 M	***77 M***
Up to Date - Braidwood	2.2 M	8.4 M	11.9 M	11.4 M	12.6 M	11.0 M	9.3 M	***67 M***
#Δ	***-2.2 M***	***-1.8 M***	***-1.1 M***	***-1.5 M***	***-1.5 M***	***-1.5 M***	***-1.2 M***	***-11 M***
%Δ	***-50%***	***-18%***	***-8%***	***-12%***	***-11%***	***-12%***	***-12%***	***-14%***

Source: NIH CISNET, U.S. Census Bureau, Capitol Policy Partners

What If We're Right: Unanswered Questions

Even if our base case expectations hold and SCOTUS is inclined to maintain the ACA's USPSTF coverage mandates by severing the "insulating" provision cited above, we still foresee several points of uncertainty that would need to be overcome.

1. The original Supreme Court petition was filed by the Biden HHS / DOJ, but next week's inauguration means that it would now fall to the *Trump administration* to defend the ACA in court, with the opposing side represented by the MAGA-aligned America First Legal Foundation. Should Trump decline, it is therefore possible that proceedings must be delayed for the Court to allow another attorney, such as one of the 24 state attorneys general who filed a supporting amicus brief, to defend the Biden team's perspective.

2. Presumably, HHS would still be required to ratify USPSTF member appointments and their recommendations to trigger associated coverage mandates. While we *suspect* the Trump administration would be hesitant to countermand findings that have long supported patient benefits, the unconventional views of Robert F. Kennedy, Jr. make it more unclear as to whether this would be the case for *all* current members and policies. We nevertheless suspect that the status quo would persist while such considerations are made.

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