On June 15, 2022, the US Supreme Court issued its opinion in *American Hospital Association v Becerra*, a ruling that not only will protect 340B hospitals and clinics from “immense economic consequences” but also preserves—at least for now—a longstanding administrative law doctrine: *Chevron* deference, which permits federal agencies to function more effectively.1 Ultimately, a seemingly technical legal case that failed to attract widespread public attention proved to be highly meaningful to both the US health care system and the administrative agencies of the executive branch, which exercise enormous influence across a broad range of policy areas.

In a previously published Viewpoint,2 the coauthors and I described the 340B Drug Discount Program that became law in 1992 as a key provision of the Public Health Service Act (Public Law 78-410).3 The law requires that pharmaceutical manufacturers participating in Medicaid provide deep discounts (20%-50%) to 340B hospitals and clinics (covered entities) on outpatient (Medicare Part B) drugs that they purchase. Covered entities, of which there are now approximately 50 000 nationwide, are health care institutions that generally serve underprivileged populations. In 2020, the estimated total discounted purchases by 340B-covered entities amounted to $38 billion.4

The Medicare Modernization Act of 2003 (Public Law 108-173) stipulates 2 options for the US Department of Health and Human Services (HHS) to reimburse 340B-covered entities for outpatient drugs.5 To use option 1, the HHS must perform surveys of hospitals to gather data on their actual drug costs and reimburse them based on the average acquisition cost of the drugs. Option 1 permits the HHS to vary reimbursement rates for different hospital groups. However, if the HHS does not perform these surveys, it must reimburse 340B-covered entities according to option 2, the average sales price of each drug plus 6%. Although the statute stipulates that HHS may adjust the reimbursements in option 2, there is no language suggesting that the agency may vary reimbursements among hospitals. Because HHS has never actually conducted the surveys required for option 1, it has always relied on reimbursement procedures according to option 2.

With either option, 340B-covered entities are provided a generous reimbursement, substantially higher than their actual costs for the drugs, and they utilize the reimbursements to subsidize other clinical programs for underprivileged patients. However, in 2018, HHS unilaterally decided to reduce the option 2 reimbursement formula from average sales price plus 6% to average sales price minus 22.5%. This was done, the agency claimed, to better align reimbursements with actual drug costs. The HHS stated that the generous reimbursements incentivize 340B-covered entities to purchase more expensive drugs (eg, costly oncology drugs). The modified reimbursement formula generated a financial loss of $1.6 billion per year for 340B-covered entities.

On behalf of these covered entities, the American Hospital Association filed a lawsuit against HHS to challenge the new reimbursement formula. The case was eventually heard by the US Supreme Court on November 30, 2021. The Court’s unanimous opinion in favor of the 340B institutions was submitted by Justice Kavanaugh just over 6 months later.1 The Court’s opinion relied principally on a careful reading of the text of the Medicare Modernization Act.

The Court ruled that the text of the statute, as stipulated by the US Congress, is clear: if HHS does not conduct surveys on drug costs, it must follow reimbursement option 2, which does not permit variation of reimbursement according to hospital group. Thus, the Court concluded that the modified reimbursement formula used by HHS for 340B-covered entities was in violation of the clear
language of the statute. The Court held that instead, 340B institutions must be reimbursed according to the average sales price of the drugs purchased plus 6%, meaning that they will be able to recuperate the large financial losses accrued since 2018.

During the oral argument, the justices and counsel for both parties debated whether Chevron deference should apply in this case. This doctrine was derived from a 1984 Supreme Court case, Chevron USA Inc. v Natural Resources Defense Council. Justice Stevens, writing for the Court, resolved that when the language in a statute is ambiguous and a government agency has proposed a reasonable interpretation of the ambiguous language, the agency should receive deference in its interpretation. Subsequently, the doctrine of Chevron deference became a central principle of administrative law, although in recent years, it has been a source of controversy, particularly among conservatives, and the Court has been less willing to defer to federal agencies. Several of the current justices have indicated that they would be amenable to overruling Chevron, expressing concern about a possible violation of separation of powers when executive branch agencies receive deference over Article III courts in interpreting statutory language. The oral arguments in American Hospital Association v Becerra left it uncertain whether the doctrine of Chevron deference might be modified or even overturned in the case.

Although Chevron was conspicuous by its absence in Justice Kavanaugh’s opinion—indeed, it was not cited a single time—it is not clear what will happen in the future. In another important case decided by the Supreme Court this term, West Virginia v Environmental Protection Agency (EPA), the Court also opted to ignore Chevron. This case addressed whether the EPA has the authority to regulate industry-wide power plant emissions by selecting the best systems of energy production. Without invoking Chevron, the Court ruled that this was a major question that could not be deferred to the EPA. By ruling in this manner, the Court indicated that it may use the major questions doctrine to avoid deferring essentially any judgment to federal agencies, including those related to health care. In fact, the major questions doctrine rose to prominence in Food & Drug Administration v Brown & Williamson, a Supreme Court case in which the agency was denied the authority to regulate tobacco. Although the Court has still not firmly settled the status of Chevron, in light of the Court’s opinion in West Virginia, the doctrine will remain under substantial pressure. It is noteworthy that a prominent legal scholar, Cass Sunstein, recently wrote, “Whether or not Chevron was right when it was originally decided, the arguments for overruling it are weak. If it were overruled, there would be a degree of chaos, at least in the short run...” Even without overruling Chevron, the Court appears poised to pursue a strategy of simply ignoring it altogether.

Because of the Court’s opinion in American Hospital Association v Becerra, 340B-covered entities may now breathe a sigh of relief. However, also as a consequence of this case and West Virginia, federal agencies (including health care agencies) that have relied on Chevron deference to resolve legal disputes in their favor may have effectively lost this important doctrinal tool. The American Hospital Association v Becerra case is a distinctive example of how a seemingly minor and technical Supreme Court decision may nonetheless have extraordinarily important implications for US society and the law.
REFERENCES