The medical profession and the 2022–2023 Term of the Supreme Court

In this year's SCOTUS review, the authors cover the case of Students for Fair Admissions, prescription costs, and the extent of genus patents, as well as provide commentary on case decisions in the most recent Term

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The 2022–2023 Term of the Supreme Court illustrates how important the Court has become to health-related matters, including decisions regarding the selection and training of new professionals, the daily practice of medicine, and the future availability of new drugs. The importance of several cases is reinforced by the fact that major medical organizations filed *amicus curiae* ("friend of the court") briefs in those cases.

Amicus briefs are filed by individuals or organizations with something significant to say about a case to the court—most often to present a point of view, make an argument, or provide information that the parties to the case may not have communicated. *Amicus* briefs are burdensome in terms of the time, energy, and cost of preparing and filing. Thus, they are not undertaken lightly. Medical organizations submitted *amicus* briefs in the first 3 cases we consider.

Admissions, race, and diversity

The case: *Students for Fair Admissions v President and Fellows of Harvard College*

The American College of Obstetricians and Gynecologists (ACOG) joined an *amici curiae* brief in *Students for Fair Admissions v President and Fellows of Harvard College* (and the University of North Carolina [UNC]).[1] This case challenged the use of racial preferences in college admissions. The Association of American Medical Colleges (AAMC) was the lead organization; nearly 40 other health-related organizations joined the brief.

The legal claim. Those filing the suits asserted that racial preferences by public colleges violate the 14th Amendment's Equal Protection Clause ("no state shall deny to any person … the equal protection of the law"). That

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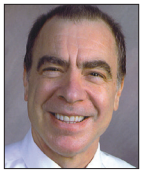

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is, if a state university gives racial preferences in selective admissions, it denies some other applicant the equal protection of the law. As for private schools (in this case, Harvard), Title VI of the Civil Rights Act of 1964 has the same standards as the Equal Protection Clause. Thus, the Court consolidated the cases and used the same legal standard in considering public and private colleges (with "colleges" including professional and graduate programs as well as undergraduate institutions).

Background. For nearly 50 years, the Supreme Court has allowed limited racial preferences in college admissions. Those preferences could only operate as a plus, however, and not a negative for applicants and be narrowly tailored. The measure was instituted temporarily; in a 2003 case, the Court said, "We expect that 25 years from now, the use of racial preferences will no longer be necessary."[2]

Decision. In a 6-3 decision, the Court held (in the UNC case) that racial preferences generally violate the Constitution, and by a 6-2 decision (in the Harvard case) these preferences violate the Civil Rights Act of 1964. (Justice Jackson was recused in the Harvard case because of a conflict.) The opinion covered 237 pages in the *US Reports*, so any summary is incomplete.

The majority concluded, "The Harvard and UNC admissions programs cannot be reconciled with the guarantees of the Equal Protection Clause. Both programs lack sufficiently focused and measurable objectives warranting the use of race, unavoidably employ race in a negative manner, involve racial stereotyping, and lack meaningful end points. We have never permitted admissions programs to work in that way, and we will not do so today."[3]

There were 3 concurring opinions and 2 dissents in the case. The concurrences reviewed the history of the Equal Protection Clause and the Civil Rights Act, the damage racial preferences can do, and the explicit limits the Court said there must be on racial preferences in higher education. The dissents had a different view of the legal history of the 14th Amendment. They said the majority was turning a blind eye to segregation in society and the race-based gap in America.

As a practical matter, this case means that colleges, including professional schools, cannot use racial preferences. The Court said that universities may consider essays and the like in which applicants describe how their own experiences as an *individual* (including race) have affected their own lives. However, the Court cautioned that "universities may not simply establish through application essays or other means the regime we hold unlawful today."[3]

The *amici* brief

ACOG joined 40 other health-related organizations in filing an *amici* brief (multiple "friends") in *Students for Fair Admission*. The AAMC led the brief, with the others signing as *amici*.[4] The brief made 3 essential points: diversity in medical education "markedly improves health outcomes," and a loss of diversity "threaten[s] patients' health; medical schools engage in an intense "holistic" review of applicants for admission; and medical schools must consider applicants' "full background" (including race) to achieve their educational and professional goals.[4]

A powerful part of the brief described the medical school admissions process, particularly the very "holistic" review that is not entirely dependent on admissions scores. The brief effectively weaves the consideration of race into this process, mentioning race (on page 22) only after discussing many other admissions factors.

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In Students for Fair Admissions v President and Fellows of Harvard College *(and the University of North Carolina), the Court held that racial preferences generally violate the Constitution and that these preferences violate the Civil Rights Act of 1964*

Child custody decisions related to the Indian Child Welfare Act

The case: *Haaland v Brackeen*

The American Medical Association (AMA) and the American Academy of Pediatrics

filed a brief in *Haaland v Brackeen*[5] involving the constitutionality of the 1978 Indian Child Welfare Act (ICWA). The statute followed a terrible history of Indian children being removed from their families inappropriately, as detailed in a concurring opinion by Justice Gorsuch.[5] The two purposes of the act were to promote raising Native American children in their culture and stem the downward trend in tribal membership.

The legal claim. The Court consolidated several cases. Essentially, a 10-month-old child (A.L.M.) was placed in foster care with the Brackeens in Texas. After more than 1 year, the Brackeens sought adoption; the biological father, mother, and grandparents all supported it. The Navajo and Cherokee Nations objected and informed the Texas court that they had found alternative placement with (nonrelative) tribal members in New Mexico. The "court-appointed guardian and a psychological expert … described the strong emotional bond between A.L.M. and his foster parents." The court denied the adoption petition based on ICWA's preference for tribe custody, and the Brackeens filed a lawsuit. The Court noted that the act "requires a state court to place an Indian child with an Indian caretaker, if one is available, even if the child is already living with a non-Indian family and the state court thinks it in the child's best interest to stay there." That is, the ICWA may require a placement that the court believes is not in the child's best interest.[5]

Decision. The constitutional claim in the case was that Congress lacked the authority to impose these substantial rules on states in making child custody decisions. The Supreme Court, in a 7-2 decision, upheld the constitutionality of the ICWA. The Court found the authority primarily in Article 1, Section 8, giving Congress the power to "regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." In addition, the Court suggested that the treaty power and "principles inherent in the Constitution's structure may empower Congress to act in the field of Indian affairs."

The *amici* brief

The joint *amici* brief of the American Academy of Pediatrics (AAP) and the AMA argued that tribes are "extended families" of Native American children.[6] It noted the destructive history of removing Native American children from their families and suggested that kinship care improves children's health. To its credit, the brief also honestly noted the serious mental health and suicide rates in some tribes, which suggest issues that might arise in child custody and adoption cases.

The Court did not, in this case, take up another constitutional issue that the parties raised—whether the strong preference for Native American over non–Native American custody violates the Equal Protection Clause of the 14th Amendment. The Court said the parties to this case did not have standing to raise the issue. Justice Kavanaugh, concurring, said it was a "serious" issue and invited it to be raised in another case.[5]

False Claims Act cases

The case: Costs for SuperValu prescriptions

For physicians and health care organizations, False Claims Act (FCA) cases are an ongoing burden and, some would say, threat. (There are also *state* FCAs, but here we are discussing the *federal* act.) The federal government has recovered more than $70 billion since 1986, most from health care entities.[7] The Justice Department identifies "health care fraud" as the largest area of FCA recovery and provides annual details on frauds resulting in liability.[8]

The legal claim. One FCA case this Term involved billings SuperValu made for outpatient prescriptions in Medicare-Medicaid programs. As its "usual and customary" costs,

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it essentially reported a list price that did not include the substantial discounts it commonly gave.[9] The charge was that it "knowingly" made a false claim regarding the price of prescriptions. The question was what state of mind, or "scienter," is required for "knowingly." Should it be objective (what a reasonable person would know) or subjective (the defendant's "knowledge and subjective beliefs")?

Background. Subjective knowledge (what the defendant actually knows) may seem impossible to prove—the defendant could just say, "I did not know I was doing wrong." Over time the law has developed several ways of demonstrating "knowing." Justice Thomas, writing for a unanimous Court, held that whistleblowers or the government might prove "knowing" in 3 ways:

1. defendants "actually knew that their reported prices were not their 'usual and customary' prices when they reported them"
2. were aware of a substantial risk that their higher, retail prices were not their "usual and customary" prices and intentionally avoided learning whether their reports were accurate
3. were aware of such a substantial and unjustifiable risk but submitted the claims anyway.[9]

Of course, records of the company, information from the whistleblower, and circumstantial evidence may be used to prove any of these; it does not require the company's admission.

The Court said that if the government or whistleblowers make a showing of any of these 3 things, it is enough.

Decision. The case was returned to the lower court to apply these rules.

The *amici* brief

The American Hospital Association and America's Health Insurance Plans filed an *amici* brief.[10] It reminded the Court that many reimbursement regulations are unclear. Therefore, it is inappropriate to impose FCA liability for guessing incorrectly what the regulations mean. Having to check on every possible ambiguity was unworkable. The Court declined, however, the suggestion that defendants should be able to use any one of many "objectively" reasonable interpretations of regulations.

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False Claims Act cases are an ongoing burden to physicians and health care organizations, with the Justice Department identifying health care fraud as the largest area of FCA recovery

The case: *Polansky v Executive Health Resources*

Health care providers who dislike the FCA may find solace this Term in this second FCA case.[11]

The legal claim. Polansky, a physician employed by a medical billing company, became an "intervenor" in a suit claiming the company assisted hospitals in false billing (inpatient claims for outpatient services). The government sought to dismiss the case, but Polansky refused.

Decision. The case eventually reached the Supreme Court, which held that the government may enter an FCA case at any time and move to dismiss the case even over the objection of a whistleblower. The government does not seek to enter a case in order to file dismissal motions often. When it does so, whistleblowers are protected by the fact that the dismissal motion requires a hearing before the federal court.

An important part of this case has escaped much attention. Justices Thomas, Kavanaugh, and Barrett invited litigation to determine if allowing private whistleblowers to represent the government's interest is consistent with Article II of the Constitution.[11] The invitation will likely be accepted. We expect to see cases challenging the place of "intervenors" pursuing claims when the government has declined to take up the case. The private intervenor is a crucial provision of the current FCA, and if such a challenge were successful, it could substantially reduce FCA cases.

Criminal false claims

Another case this Term is cautionary about the consequences of health care misbilling. It resulted in a criminal charge. More importantly, in addition to a basic fraud charge, the government added a charge of aggravated identity theft,[12] which carries a mandatory 2-year prison sentence.

Dubin overbilled Medicaid for psychological testing by saying the testing was done by a licensed psychologist rather than an assistant. The government claimed the "identity theft" was using the patient's (actual) Medicaid number in submitting

the bill.[12] The Court unanimously held the overbilling was not aggravated identity theft as defined in federal law. Dubin could be convicted of fraudulent billing but not aggravated identity theft, thereby avoiding the mandatory prison term.

Patents of "genus" targets

The case: *Amgen v Sanofi*

This case, which corrected an error of the patent office, received little attention but was likely a turning point in the next generation of pharmaceuticals.[13]

Background. "Genus" patents allow a single pharmaceutical company to patent every antibody that binds to a specific amino acid on a naturally occurring protein. In this case, the patent office had granted a "genus" patent on "all antibodies" that bind to the naturally occurring protein PCSK9 and block it from hindering the body's mechanism for removing low-density lipoprotein (LDL) cholesterol from the bloodstream,[13] helping to reduce LDL cholesterol levels. These patents could involve millions of antibodies—and Amgen was claiming a patent on all of them. Amgen and Sanofi marketed their products, each with their own unique amino acid sequence.[13] Amgen sued Sanofi for violating its patent rights.

Decision. The Court unanimously held that Amgen did not have a valid patent on all antibodies targeting PCSK9, only those that it had explicitly described in its patent application—a ruling based on a 150-year-old technical requirement for receiving a patent. An applicant for a patent must include "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art…to make and use the same."[13] Amgen's patent provided the description for only a few of the antibodies, but from the description in its application others could not "make and use" all of the antibodies targeting PCSK9.

While the decision was vital for future pharmaceuticals, the patent principle on which it was based has an interesting history. The Court noted that it affected the telegraph (Morse lost part of his patent), electric lights (Edison won his case against other inventors), and the glue for wood veneering (Perkins Glue Company lost).[13]

Other notable decisions

Student loans

The Court struck down the Biden Administration's student loan forgiveness program, which would have cost approximately $430 billion.[14] The central issue was whether the administration had the authority for such massive loan forgiveness; that is, whether Congress had authorized the broad loan forgiveness. The administration claimed authority from the post–9/11 HEROES Act, which allows the Secretary of Education to "waive or modify" loan provisions during national emergencies. The temporary hold on loan payments during COVID was based on this provision. However, in a 6-3 decision, the Court held that the act did not allow the secretary to cancel $430 billion in loans. "The Act allows the Secretary to 'waive or modify' existing statutory or regulatory provisions applicable to financial assistance programs under the Education Act, not to rewrite that statute from the ground up."[14]

Free speech and the wedding web designer

303 Creative v Elenis involved a creative website designer who did not want to be required to create a website for a gay wedding.[15] The designer had strong beliefs against same-sex marriages, but Colorado sought to force her to do so under the state "public accommodations" law. In a 6-3 decision, the Court held that the designer had a "free speech" right. That is, the state could not compel her

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In Amgen v Sanofi, *the Court ruled that Amgen did not have a valid patent on all antibodies targeting PCSK9, and Sanofi was not violating Amgen's patent rights*

to undertake speech expressing things she did not believe. This was because the website design was an expressive, creative activity and therefore was "speech" under the First Amendment.

Wetlands and the Clean Water Act

The essential issue in *Sackett v Environmental Protection Agency* (EPA) was the definitions of waters of the United States and related wetlands. The broad definition the EPA used meant it had jurisdiction to regulate an extraordinary amount of territory. It had, for example, prevented the Sacketts from building a modest house claiming it was part of the "waters of the United States because they were near a ditch that fed into a creek, which fed into Priest Lake, a navigable, intrastate lake." The Court held that the EPA exceeded its statutory authority to define "wetlands."[16]

The Court held that under the Clean Water Act, for the EPA to establish jurisdiction over adjacent wetlands, it must demonstrate that[16]:

1. "the adjacent body of water constitutes waters of the United States (ie, a relatively permanent body of water connected to traditional interstate navigable waters)…"
2. "…the wetland has a continuous surface connection with that water, making it difficult to determine where the water ends, and the wetland begins."

Under this definition, the Sacketts could build their house. This was a statutory interpretation case. Therefore, Congress can expand or otherwise change the EPA's authority under the Clean Water Act and other legislation.

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Justice Ketanji Brown Jackson (who was a law clerk for Justice Breyer in the past) was sworn in as a new Supreme Court justice in June 2022, when Justice Breyer officially retired

Conclusions: A new justice, "shadow docket," and ethics rules

SCOTUS' newest member. When the Marshall called the Court into session on October 3, 2022, it had a new member, Justice Ketanji Brown Jackson. She was sworn in on June 30, 2022, when her predecessor (Justice Breyer) officially retired. She had been a law clerk for Justice Breyer in 1999, as well as a district court judge and court of appeals judge. Those who count such things described her as the "chattiest justice."[17] She spoke more than any other justice—by one count, a total of 75,632 words (an average of 1,300 words in each of the 58 arguments).

A more balanced Court? Most commentators view the Court as more balanced or less conservative than the previous Term. For example, Justice Sotomayor was in the majority 40% last Term but 65% this Term. Justice Thomas was in the majority 75% last Term but 55% this Term. Put another way, this Term in the divided cases, the liberal justices were in the majority 64% of the time, compared with the conservative justices 73%.[18] Of course, these differences may reflect a different set of cases rather than a change in the direction of the Court. There were 11 (or 12, depending on how 1 case is counted) 6-3 cases, but only 5 were considered ideological. That suggests that, in many cases, the coalitions were somewhat fluid.

"Shadow docket" controversy continues.[19] Shadow docket refers to orders the Court makes that do not follow oral arguments and often do not have written opinions. The orders are all publicly available. This Term a close examination of the approximately 30 shadow docket opinions shows that the overwhelming majority were dissents or explanations about denials of certiorari. The Court ordered only a few stays or injunctions via the shadow docket. One shadow docket stay (that prevented a lower court order from going into effect) is particularly noteworthy. A federal judge had ordered the suspension of the distribution of mifepristone while courts considered claims that the US Food and Drug Administration (FDA) had improperly approved the drug. In a shadow docket order, the Court issued the stay to allow mifepristone to be sold while the case challenging its approval was heard.[20] The only opinion was a dissent from Justice Alito. But it also demonstrates the importance of the shadow docket. Without this intervention, in at least part of the country, the distribution of mifepristone would have been interrupted pending the outcome of the FDA cases.

In August, the Court delayed a settlement in the Purdue Pharma liability

bankruptcy case.[21] It also stayed an injunction of a lower court, thereby permitting federal "ghost guns" regulations to go into effect at least temporarily.[22]

More ethics rules to come? Another area in which the Court faced criticism was formal ethics rules. The justices make financial disclosures, but these are somewhat ambiguous. There is likely to be increasing pressure for a more complete disclosure of non-financial relationships and more formal ethics rules. ●

Coming attractions: Next Term

The Court had, by September 1, 2023, accepted 22 cases for hearing next Term.[1] The cases include a challenge to the extraordinary funding provision for the Consumer Financial Protection Bureau, another racial challenge to congressional districts (South Carolina), the status of Americans with Disability Act "testers" who look for violations without ever intending to use the facilities, the level of deference courts should give to interpreting federal statutes (so-called "*Chevron*" deference), the opioid (OxyContin) bankruptcy, and limitations on gun ownership. This represents less than half of the cases the Court will likely hear next Term, so the Court will add many more cases to the docket. It promises to be an appealing Term.

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This Term, the liberal justices were in the majority 64% of the time, and the conservative justices were in the majority 73% of the time

For *Other interesting decisions made by SCOTUS* see the online version of this article at **mdedge.com/obgyn**

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Other interesting decisions made by SCOTUS

When the Court adjourned on June 30, 2023, it had considered 60 cases, plus hundreds of petitions asking it to hear cases. Most commentators count 55 cases decided after briefing and oral argument and where there was a signed opinion. The information below uses 55 cases unless otherwise noted. During the 2022–2023 Term, the Court:

- upheld liability for the involuntary administration of psychotropic drugs in nursing home [1]
- permitted disabled students, in some instances, both to make Individuals with Disabilities Education Act (IDEA) claims for services and to file Americans with Disabilities Act (ADA) lawsuits against their schools[2]
- upheld a statute that makes it illegal to "encourage or induce an alien to come to, enter, or reside in the United States, knowing or in reckless disregard of the fact that such coming to, entry, or residence is or will be in violation of law." The defendant had used a scam promising noncitizens "adult adoptions" (of which there is no such thing) making it legal for them to come to and stay in the United States.[3]
- narrowed the "fair use" of copyrighted works. It held that Andy Warhol's use of a copyrighted photograph in his famous Prince prints was not "transformative" in a legal sense largely because the photo and prints "share the same use"—magazine illustrations.[4]
- in another intellectual property case, held that Jack Daniel's might sue a dog toy maker for a rubber dog toy that looked like a Jack Daniel's bottle[5]
- further expanded the Federal Arbitration Act by holding that a federal district court must immediately stay court proceedings if one party is appealing a decision not to require arbitration[6]
- held that two social media companies were not responsible for terrorists using their platforms to recruit others to their cause. It did not, however, decide whether §230 of the Communication Decency Act protects companies from liability.[7]
- made it easier for employees to receive accommodation for their religious practices and beliefs. Employers must make religious accommodations unless the employer can show that "the burden of granting an accommodation would result in substantial increased [financial and other] costs in relation to the conduct of its particular business."[8]
- declined to hear an appeal from Johnson & Johnson (through a subsidiary, Ethicon) about pelvic mesh. In this case, the California Attorney General filed a lawsuit against Ethicon for false advertising by failing to detail the risks of pelvic mesh. The lower courts estimated 240,000 written violations of the law by Ethicon between 2008 and 2017. The trial and appeal to California courts resulted in a judgment of $302 million against Johnson & Johnson. The company asked the Court to review that judgment, but the Court denied *certiorari*. That likely means the $302 million is final.

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