Results | Of 2724 generic applications (including those not CGT-eligible), 283 (10.4%) requested CGT designation (89 applicants for 292 unique products). Overall, 429 product-applicant pairs, 92 for complex products, requested CGT designation; of the 429 pairs, 320 (74.6%) were granted CGT designation (**Table**) and 109 (25.4%) were denied designation either because requests were not made in accordance with statutory time frames (61.5%) or because there was adequate competition (38.5%).

Of the 320 product-applicant pairs granted CGT designation, 114 product-applicant pairs (35.6%), for 86 unique products, had been approved at the time of analysis. Among those 86 unique generic products, 63 (73.3%) were eligible for exclusivity at approval.[3] Of these 63 products, 54 (85.7%) marketed within a median of 2.5 (IQR, 0-9.5) days of approval; the remaining did not market within 75 days of approval, forfeiting exclusivity.

Of the 114 approved product-applicant pairs with CGT designation, 51 pairs accounting for 23 unique products were not eligible for exclusivity at approval because another applicant for the product was approved first (30/51 [58.8%]) or because the reference drug had unexpired patents or exclusivities at generic application submission (21/51 [41.2%]) (patent/exclusivity had been resolved at generic approval).

Discussion | A sizable fraction of generic applicants requested CGT designation, and many drugs approved with CGT exclusivity eligibility marketed within 2.5 days after approval, which can benefit the health care system and patients.

CGT generics enhance previously inadequate competition, and generics typically decrease drug prices.[4] Although several competing generics are needed to achieve floor prices, 30% reductions can occur with 1 competing generic, potentially increasing patient access to affordable drugs.[5] Moreover, because CGT encourages an additional manufacturer for a sole-source drug product, it may limit indiscriminate drug price increases.[6]

Limitations include not analyzing if generics approved with CGT exclusivity affect drug prices, and findings cannot be generalized to other types of FDA applications.

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COVID-19 Incidence and Mortality in Federal and State Prisons Compared With the US Population, April 5, 2020, to April 3, 2021

Early in the COVID-19 pandemic, case and death rates in US prisons substantially exceeded national rates.[1] Prison systems subsequently reported adopting several policies to contain COVID-19 spread, including limiting social interactions, distributing personal protective equipment, and expediting prisoner releases,[2,3] although failures of infection prevention and control have been documented.[2,4] We examined COVID-19 cases and deaths among US federal and state prisoners during the first 52 weeks of the pandemic and compared these rates with the overall US population, updating a previously published report analyzing COVID-19 incidence and mortality in prisons through June 6, 2020.[1]

Methods | Counts of COVID-19 cases and deaths among prisoners in all 50 state prison systems and the Federal Bureau of Prisons were collected by the UCLA Law COVID Behind Bars

Data Project for 52 weeks from April 5, 2020, to April 3, 2021. Counts were extracted from departments of corrections websites and, as needed, supplemented with data collected by the Marshall Project and the Associated Press.[5] To calculate rates of COVID-19 in prisons, we used total jurisdictional prison population data reported by the Vera Institute[3] for January 1, 2020, July 1, 2020, December 30, 2020, and March 31, 2021. We estimated weekly prison populations by linearly interpolating between the observed dates. For comparison, we also calculated US population COVID-19 rates using cases and deaths reported by the Centers for Disease Control and Prevention,[6] allowing for a 2-month reporting delay. US population data were taken from the US Census Bureau's American Community Survey 2019.

We calculated both weekly and cumulative rates of incidence and standardized mortality for the prison population and US population. Weekly prison rates were calculated using the jurisdictional incarcerated population for the corresponding week, while cumulative rates were calculated using the 52-week mean population size. Standardized mortality rates were calculated, adjusting for age and sex with indirect standardization, as described in a previous report.[1] All analysis was performed using R version 4.1.0. The UCLA institutional review board deemed this study to be exempt.

Table. Demographic Characteristics and COVID-19 Statistics for the Overall US Population and Prison Population

Characteristics	US population	Prison population
Population, No.	328 200 000[a]	1 280 263[b]
Aged ≥65 y, %	16[a]	3[c]
Male sex, %	49[a]	93[c]
COVID-19 incidence		
Cases, No.[d]	30 688 676[e]	394 066[f]
Incidence rate per 100 000	9350.6	30 780.1
COVID-19 mortality		
Deaths, No.[d]	554 323[e]	2555[f]
Crude mortality rate per 100 000	168.9	199.6[g]
Standardized mortality rate per 100 000	80.9	199.6[g]

[a] Derived from 2019 US Census Bureau data (https://www.census.gov/data/tables/2019/demo/age-and-sex/2019-age-sex-composition.html). The US population includes the prison population.

[b] Estimated from Kang-Brown et al.[3]

[c] Derived from 2019 published estimates from US Bureau of Justice statistics (https://www.bjs.gov/content/pub/pdf/p19.pdf).

[d] COVID-19 cases and deaths are cumulative counts up to April 3, 2021.

[e] From the Centers for Disease Control and Prevention (https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-bySex-Age-and-S/9bhg-hcku).

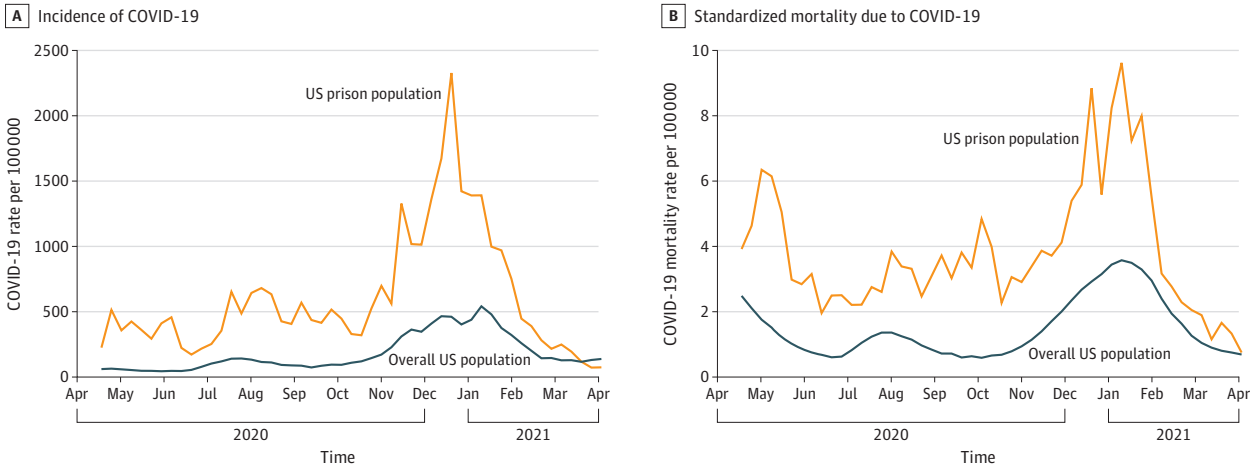
[f] From the UCLA Law COVID Behind Bars Data Project (https://uclacovidbehindbars.org).

[g] Indirect standardization was used; thus, prison population crude and standardized mortality rates are equal.

Results | By April 3, 2021, 394 066 COVID-19 cases and 2555 deaths due to COVID-19 had been reported among the US prison population (**Table**). The cumulative incidence rate per 100 000 persons was 30 780 cases for the prison population and 9350 cases for the US population, with a prison-to-US cumulative incidence ratio of 3.3 (95% CI, 3.3-3.3). The standardized mortality rate per 100 000 persons was 199.6 deaths for the prison population and 80.9 deaths for the US population (Table), with a prison-to-US standardized cumulative mortality rate ratio of 2.5 (95% CI, 2.3-2.7).

The prison population weekly incidence rate peaked during the week of December 13, 2020, when there were 2327 new cases per 100 000 persons. The standardized mortality rate peaked during the week of January 3, 2021, with 9.6 new deaths per 100 000 persons (**Figure**). During

Figure. Weekly COVID-19 Incidence Rates and Standardized Mortality Rates in US Prisons and in the Overall US Population From April 5, 2020, to April 3, 2021



Mortality rates are adjusted for age and sex. The incidence rate peaked for the prison population the week of December 13, 2020, while the mortality rate peaked the week of January 3, 2021, with values of 2327 new cases and 9.6 deaths per 100 000 individuals, respectively.

these weeks, the prison-to-US incidence rate ratio was 5.0 (95% CI, 5.0-5.1), while the standardized mortality ratio was 2.7 (95% CI, 1.9-3.8).

Discussion | COVID-19 incidence and standardized mortality rates remained consistently higher among the prison population than the overall US population in the first year of the pandemic. While COVID-19 incidence and mortality rates peaked in late 2020 and early 2021 and have since declined, the cumulative toll of COVID-19 has been several times greater among the prison population than the overall US population.

A study limitation is reliance on publicly available data, which are subject to potential misreporting, delays,[4] and inconsistencies in population estimates.[3] In addition, differences in testing rates between the overall US population and the prison population may have biased incidence ratios. Also, the study period did not capture the more recent outbreak of COVID-19 cases due to the Delta variant. Nevertheless, this study underscores the importance of initiatives such as vaccination, decarceration, and continued disease surveillance in prison settings as long as the pandemic continues.

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Medical Specialty Board Parental, Caregiver, and Medical Leave Policy Updates After 2021 American Board of Medical Specialties Mandate

Parental, caregiver, and medical leave is essential for the well-being of medical trainees and their families. However, leave may be limited by ambiguous or restrictive policies or underused because trainees may fear the consequences of taking leave, including required "make-up" time resulting in delayed graduation.[1-3] Effective July 1, 2021, the American Board of Medical Specialties (ABMS) mandated member boards to allow residents in programs with durations of 2 years or longer "a minimum of 6 weeks…parental, caregiver and medical leave at least once during training without exhausting all other allowed time away from training and without extending training."[4] We assessed if and how boards adhered to this mandate, board policy variability, and changes compared with prior policies.

Methods | This study was deemed not human subjects research by the Mass General Brigham institutional review board. We reviewed publicly accessible websites for leave policies related to residency training requirements and eligibility for Initial Certification for ABMS boards on October 21, 2021. Boards were contacted by email to verify that the listed policy was current. A board's policy was deemed adherent to the ABMS mandate if a minimum of 6 weeks of leave in addition to vacation was possible with the policy as worded. Variables analyzed included requirements related to time and need for training extension, relationship of parental, caregiver, and medical leave to other nonclinical time or time off, and changes since 2018.[2] Maximum allowable leave across all boards for which data were available, normalized by training duration, was compared between 2018 and 2021 and between surgical and nonsurgical specialties using the 2-tailed Mann-Whitney test. Analysis was performed with GraphPad Prism version 9. A $P < .05$ was deemed statistically significant.

Results | All 23 boards (100%) with 2-year or longer training pathways had policies that adhered to the ABMS mandate, although policies were variable. One board policy (4%) relied on the discretion of the program director or institutional policy