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FULL FDA APPROVAL OF PFIZER/BIONTECH COVID-19 VACCINE

PATIENT IMPACT STATEMENT

AMERICAN ASSOCIATION OF KIDNEY PATIENTS (AAKP)

AMERICA'S LARGEST ORGANIZATION OF KIDNEY TRANSPLANT RECIPIENTS AND LIVING ORGAN DONORS

WASHINGTON, **D.C.** – The American Association of Kidney Patients (AAKP), the largest independent kidney patient organization in the nation, issued a formal statement in support of today's announcement by the U.S. Food and Drug Administration (FDA) that the agency had granted, based on additional safety and efficacy data, full approval of the Pfizer/BioNTech vaccine for COVID-19. The Pfizer/BioNTech vaccine, and two other COVID-19 vaccines, have been available over the course of the past year under FDA's emergency use authorization (EUA).

"The American Association of Kidney Patients (AAKP) thanks the U.S. Food and Drug Administration (FDA) for granting full authorization for the Pfizer/BioNTech vaccine and we hope FDA completes their safety and efficacy review for other COVID-19 vaccines with a sense of urgency. As our nation battles the pandemic and the highly transmissible Delta variant, unvaccinated Americans continue to be at high-risk of contracting the disease and suffering from severe complications, including Acute Kidney Injury (AKI), lengthy hospitalizations, and death. Just as importantly, unvaccinated Americans pose an extremely serious risk to their families, friends, and communities; especially to people whose unique vulnerabilities to COVID-19 infection are not visible. These people include immunosuppressed kidney transplant recipients and immunocompromised patients managing severe chronic diseases and other medical conditions.

It is our hope that every American will gain confidence from FDA's announcement, consult with their doctors, act responsibly, and secure their vaccinations if they have not already done so. As kidney patients, we understand what it means to involuntarily forfeit good health to disease, spend years on an organ transplant waiting list, have life expectancy shortened by the brutality of dialysis, and watch those who love us suffer. Please take advantage of the miraculous gift vaccines provide you and your family to avoid serious illness, the destruction of your dreams and aspirations, and the senseless and completely avoidable loss of yet another human life.

As Americans, we must unite and maintain our empathy for one another to defeat this pandemic and we must stand together above the cynics who seek to erode our common belief in the rights and dignity of every individual in our society."

On August 15, 2021, the FDA announced their authorization of a third dose of COVID-19 vaccines for highly vulnerable immunocompromised patients, such as kidney transplant recipients, whose lives depend upon immunosuppressive drug therapies and for whom current vaccines have not generated a sufficient antibody response. AAKP also issued a Patient Impact Statement in support of that FDA decision (<u>read here</u>). Since early 2020 and the start of the COVID-19 crisis, AAKP has executed an extensive national and global education campaign on the dangers of COVID-19 to all people and the need for greater medical innovation and more inclusive clinical trials to develop vaccines that fight the virus and emerging variants. AAKP content on COVID-19 can be found here https://bit.ly/AAKPCoronavirusResources.

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About the American Association of Kidney Patients (AAKP): Founded in 1969, AAKP is the largest kidney patient organization driving policy discussions on kidney patient consumer care choice and treatment innovations. By 1973, AAKP patient collaborations with the U.S. Congress and White House helped gain passage of dialysis coverage for any person suffering kidney failure, creating the only disease specific, taxpayer-funded entitlement program in America. That program, the End Stage Renal Disease Program (ESRD) administered by CMS, has saved over one million lives. In the past decade, AAKP patients have helped gain lifetime transplant drug coverage for kidney transplant recipients (2020); new patient-centered policies via the White House Executive Order on Advancing American Kidney Health (2019); new job protections for living organ donors under the Family Medical Leave Act (FMLA) from the U.S. Department of Labor (2018); and Congressional legislation allowing HIV-positive organ transplants for HIV-positive patients (2013). AAKP virtual platforms and social networks are internationally known for their impact. Follow AAKP on social media at @kidneypatient on Facebook and @kidneypatients on Twitter and visit our website at https://aakp.org/.