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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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If the U.S. Department of Health and Human Services (HHS) were a separate country, its approximately $1.6 trillion budget would rank as the world's fifth-largest national budget. For good or ill, HHS activities personally impact the lives of more Americans than do those of any other federal agency. Under President Trump, HHS was dedicated to serving "all Americans from conception to natural death, including those individuals and families who face...economic and social well-being challenges."[1] Under President Biden, the mission has shifted to "promoting equity in everything we do" for the sake of "populations sharing a particular characteristic" including race, sexuality, gender identification, ethnicity, and a host of other categories.[2]

As a result of HHS's having lost its way, U.S. life expectancy, instead of returning to normal after the COVID-19 pandemic, continued to drop precipitously to levels not seen since 1996 with white populations alone losing 7 percent of their expected life span in just one year.[3] Nothing less than America's long-term survival is at stake. Accordingly, HHS must return to serving the health and well-being of all Americans at all stages of life instead of using social engineering that leaves us sicker, poorer, and more divided.

OVERVIEW

HHS consists of 11 operating divisions that have varying degrees of practical independence from the Secretary of Health and Human Services and 15 staff divisions that are directly under the Office of the Secretary. This chapter's recommendations are limited to those divisions that most need reform and address, wherever possible, five cross-cutting goals.

Goal #1: Protecting Life, Conscience, and Bodily Integrity. The Secretary should pursue a robust agenda to protect the fundamental right to life, protect conscience rights, and uphold bodily integrity rooted in biological realities, not ideology.

From the moment of conception, every human being possesses inherent dignity and worth, and our humanity does not depend on our age, stage of development, race, or abilities. The Secretary must ensure that all HHS programs and activities are rooted in a deep respect for innocent human life from day one until natural death: Abortion and euthanasia are not health care.

A robust respect for the sacred rights of conscience, both at HHS and among governments and institutions funded by it, increases choices for patients and program beneficiaries and furthers pluralism and tolerance. The Secretary must protect Americans' civil rights by ensuring that HHS programs and activities follow the letter and spirit of religious freedom and conscience-protection laws.

Radical actors inside and outside government are promoting harmful identity politics that replaces biological sex with subjective notions of "gender identity" and bases a person's worth on his or her race, sex, or other identities. This destructive dogma, under the guise of "equity," threatens American's fundamental liberties as well as the health and well-being of children and adults alike. The next Secretary must ensure that HHS programs protect children's minds and bodies and that HHS programs respect parents' basic right to direct the upbringing, education, and care of their children.

Goal #2: Empowering Patient Choices and Provider Autonomy. Basic economics holds that costs tend to decrease and quality and options tend to increase when there is robust and free competition in the provision of goods and services. Health care is no exception. Health care reform should be patient-centered and market-based and should empower individuals to control their health care–related dollars and decisions.

Of course, providers who deliver health care also need the freedom to address the unique needs of their patients. States should be the primary regulators of the medical profession, and the federal government should not restrict providers' ability to discharge their responsibilities or limit their ability to innovate through government pricing controls or irrational Medicare and Medicaid reimbursement schemes.

Finally, America's broken insurance system, run largely through confusing provider networks and third-party payers (employers), induces overconsumption of health care, limits consumer shopping, and hides true costs from patients.

The federal government should focus reform on reducing burdens of regulatory compliance, unleashing innovation in health care delivery, ceasing interference in the daily lives of patients and providers, allowing alternative insurance coverage options, and returning control of health care dollars to patients making decisions with their providers about their health care treatments and services.

Goal #3: Promoting Stable and Flourishing Married Families. Families comprised of a married mother, father, and their children are the foundation of a well-ordered nation and healthy society. Unfortunately, family policies and programs under President Biden's HHS are fraught with agenda items focusing on "LGBTQ+ equity," subsidizing single-motherhood, disincentivizing work, and penalizing marriage. These policies should be repealed and replaced by policies that support the formation of stable, married, nuclear families.

Working fathers are essential to the well-being and development of their children, but the United States is experiencing a crisis of fatherlessness that is ruining our children's futures. In the overwhelming number of cases, fathers insulate children from physical and sexual abuse, financial difficulty or poverty, incarceration, teen pregnancy, poor educational outcomes, high school failure, and a host of behavioral and psychological problems. By contrast, homes with non-related "boyfriends" present are among the most dangerous place for a child to be. HHS should prioritize married father engagement in its messaging, health, and welfare policies.

In the context of current and emerging reproductive technologies, HHS policies should never place the desires of adults over the right of children to be raised by the biological fathers and mothers who conceive them. In cases involving biological parents who are found by a court to be unfit because of abuse or neglect, the process of adoption should be speedy, certain, and supported generously by HHS.

Goal #4: Preparing for the Next Health Emergency. The COVID-19 pandemic demonstrated how catastrophic a micromanaging, misinformed, centralized, and politicized federal government can be. Basic human rights, medical choice, and the doctor–patient relationship were trampled without scientific justification and for extended periods of time. Excess deaths, not due to COVID-19, skyrocketed because of forced lockdowns, isolation, vaccine-related mass firings, and colossal disruptions of the economy and daily rhythms of life.

The federal government's public health apparatus has lost the public's trust. Before the next national public health emergency, this apparatus must be fundamentally restructured to ensure a transparent, scientifically grounded, and more nimble, efficient, transparent, and targeted response that respects the unique needs and input of patient populations and providers.

Every one of the overreaching policies during the pandemic—from lockdowns and school closures to mask and vaccine mandates or passports—received its supposed legal justification from the state of emergency declared (and renewed) by the HHS Secretary. Tellingly, however, the threshold for what constitutes a public health emergency—how many cases, hospitalizations, deaths, etc.—was never defined. For the sake of democratic accountability, we must know with clarity what will trigger the next emergency declaration and, just as important, what will trigger its end.

Unaccountable bureaucrats like Anthony Fauci should never again have such broad, unchecked power to issue health "guidelines" that will certainly be the basis for federal and state mandates. Never again should public health bureaucrats be allowed to hide information, ignore information, or mislead the public concerning the efficacy or dangers associated with any recommended health interventions because they believe it may lead to hesitancy on the part of the public. The only way to restore public trust in HHS as an institution capable of acting responsibly during a health emergency is through the best of disinfectants—light.

Goal #5: Instituting Greater Transparency, Accountability, and Oversight. The next Administration should guard against the regulatory capture of our public health agencies by pharmaceutical companies, insurers, hospital conglomerates, and related economic interests that these agencies are meant to regulate. We must erect robust firewalls to mitigate these obvious financial conflicts of interest.

All National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration regulators should be entirely free from private biopharmaceutical funding. In this realm, "public–private partnerships" is a euphemism for agency capture, a thin veneer for corporatism. Funding for agencies and individual government researchers must come directly from the government with robust congressional oversight.

We must shut and lock the revolving door between government and Big Pharma. Regulators should have a long "cooling off period" on their contracts (15 years would not be too long) that prevents them from working for companies they have regulated. Similarly, pharmaceutical company executives should be restricted from moving from industry into positions within regulatory agencies.

Finally, HHS should adopt metrics across the agency that can objectively determine the extent to which the agency's policies and programs achieve desired health and welfare outcomes (not agency outputs). What is not measured is not achieved.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

COVID and Structural Reform. COVID-19 exposed the Centers for Disease Control and Prevention (CDC) as perhaps the most incompetent and arrogant agency in the federal government. CDC continually misjudged COVID-19, from its lethality, transmissibility, and origins to treatments. We were told masks were not needed; then they were made mandatory. CDC botched the development of COVID tests when they were needed most. When it was too late, we were told to put our lives on hold for "two weeks to flatten the curve;" that turned into two years of interference and restrictions on the smallest details of our lives. Congress should ensure that CDC's legal authorities are clearly defined and limited to prevent a recurrence of any such arbitrary and vacillating exercise of power.

The CDC should be split into two separate entities housing its two distinct functions. On the one hand, the CDC is now responsible for collecting, synthesizing,

and publishing epidemiological data from the individual states—a scientific data-gathering function. This information is crucial for medical and public health researchers around the country. On the other hand, the CDC is also responsible for making public health recommendations and policies—an inescapably political function. At times, these two functions are in tension or clear conflict. In February 2022, for example, it was reported that "[t]wo full years into the pandemic, the agency leading the country's response to the public health emergency has published only a tiny fraction of the data it has collected," much of which "could [have helped] state and local health officials better target their efforts to bring the virus under control." A CDC spokesman said that one of the reasons was "fear that the information might be misinterpreted."[4]

These distinct functions should be separated into two entirely separate agencies with a firewall between them. We need a national epidemiological agency responsible only for publishing data and required by law to publish all of the data gathered from states and other sources. A separate agency should be responsible for public health with a severely confined ability to make policy recommendations. The CDC can and should make assessments as to the *health* costs and benefits of health interventions, but it has limited to no capacity to measure the *social* costs or benefits they may entail. For example, how much risk mitigation is worth the price of shutting down churches on the holiest day of the Christian calendar and far beyond as happened in 2020? What is the proper balance of lives saved versus souls saved? The CDC has no business making such inherently political (and often unconstitutional) assessments and should be required by law to stay in its lane.

The CDC's initial COVID-19 testing failures were largely the result of that agency's prioritizing its own development and production of tests using its internal staff and facilities. The private sector is much better positioned to tackle the challenges inherent in developing and manufacturing novel products, as illustrated by the relative success of the alternative approach to facilitating the development of COVID-19 vaccines and therapeutics by private companies that was adopted by the Food and Drug Administration (FDA).

When it comes to testing, the CDC's role should similarly be to facilitate rather than supplant the efforts of private test developers, academic laboratories, state public health laboratories, and clinical testing providers. When responding to a novel pathogen, the CDC should focus on gathering and disseminating information, including specimens needed for development of positive controls and reference panels, and ensuring that test developers can develop and validate diagnostic tests. These changes will require a shift in priorities and culture at the CDC—and throughout HHS more broadly.[5]

Most problematically, the CDC presented itself as a kind of "super-doctor" for the entire nation. The CDC is a public health institution, not a medical institution. According to its mission statement, the agency focuses on "disease prevention and

control, environmental health, and health promotion and health education activities."[6] It is not qualified to offer (and usually does not purport to offer) professional medical opinions applicable to specific patients.

From time to time, the CDC offers findings and recommendations that competent medical practitioners often will consider in arriving at a professional medical judgment for a particular patient. In this respect, CDC guidelines are analogous to guidelines from other public health associations or medical societies: They are informative, not prescriptive.

By statute or regulation, CDC guidance must be prohibited from taking on a prescriptive character. For example, never again should CDC officials be allowed to say in their official capacity that school children "should be" masked or vaccinated (through a schedule or otherwise) or prohibited from learning in a school building. Such decisions should be left to parents and medical providers. We have learned that when CDC says what people "should" do, it readily becomes a "must" backed by severe punishments, including criminal penalties. CDC should report on the risks and effectiveness of all infectious disease-mitigation measures dispassionately and leave the "should" and "must" policy calls to politically accountable parties.

Conflicts of Interest. There was a time when the CDC could not take money from the pharmaceutical industry, but in 1992, the agency discovered a loophole in federal law that allowed it to accept pharma contributions through the nonprofit CDC Foundation. The money started flowing immediately: From 2014 through 2018, the CDC Foundation received $79.6 million from pharmaceutical corporations like Pfizer, Biogen, and Merck.[7] This practice presents a stark conflict of interest that should be banned.

Data Systems. The COVID-19 pandemic has revealed the disastrous public health consequences of the CDC's failure to follow multiple congressional mandates to modernize its data infrastructure. Current reporting methods are burdensome for frontline medical workers, yet they result only in fragmented data that are not available in real time or usable across systems.

Congress should require HHS to prioritize the electronic collection and dissemination of robust, privacy-protected data that better leverages existing systems while reducing burdens on clinicians. HHS should also enter into a public–private partnership with a data-management expert to develop a system that makes critical information available to health care workers and policymakers in real time.[8]

The CDC operates several programs related to vaccine safety including the Vaccine Adverse Event Reporting System (VAERS); Vaccine Safety Datalink (VSD); and Clinical Immunization Safety Assessment (CISA) Project. Those functions and their associated funding should be transferred to the FDA, which is responsible for post-market surveillance and evaluation of all other drugs and biological products.

Respect for Life and Conscience. The CDC should eliminate programs and projects that do not respect human life and conscience rights and that undermine

family formation. It should ensure that it is not promoting abortion as health care. It should fund studies into the risks and complications of abortion and ensure that it corrects and does not promote misinformation regarding the comparative health and psychological benefits of childbirth versus the health and psychological risks of intentionally taking a human life through abortion.

The CDC oversaw and funded the development and testing of the COVID-19 vaccines with aborted fetal cell lines, insensitive to the consciences of tens of thousands to hundreds of thousands of people who objected to taking a vaccine with such a link to abortion. As evidenced by litigation across the country, it is likely that thousands were fired unjustly because of the exercise of their consciences or faith on this question, which could have been avoided with a modicum of concern for this issue from CDC. There is never any justification for ending a child's life as part of research, and the research benefits from splicing or growing aborted fetal cells and aborted baby body parts can easily be provided by alternative sources. All such research should be prohibited as a matter of law and policy.

CDC should update its public messaging about the unsurpassed effectiveness of modern fertility awareness–based methods (FABMs) of family planning and stop publishing communications that conflate such methods with the long-eclipsed "rhythm" or "calendar" methods. CDC should fund studies exploring the evidence-based methods used in cutting-edge fertility awareness.

Data Collection. The CDC's abortion surveillance and maternity mortality reporting systems are woefully inadequate. CDC abortion data are reported by states on a voluntary basis, and California, Maryland, and New Hampshire do not submit abortion data at all. Accurate and reliable statistical data about abortion, abortion survivors, and abortion-related maternal deaths are essential to timely, reliable public health and policy analysis.

Because liberal states have now become sanctuaries for abortion tourism, HHS should use every available tool, including the cutting of funds, to ensure that every state reports exactly how many abortions take place within its borders, at what gestational age of the child, for what reason, the mother's state of residence, and by what method. It should also ensure that statistics are separated by category: spontaneous miscarriage; treatments that incidentally result in the death of a child (such as chemotherapy); stillbirths; and induced abortion. In addition, CDC should require monitoring and reporting for complications due to abortion and every instance of children being born alive after an abortion. Moreover, abortion should be clearly defined as *only* those procedures that intentionally end an unborn child's life. Miscarriage management or standard ectopic pregnancy treatments should never be conflated with abortion.

Comparisons between live births and abortion should be tracked across various demographic indicators to assess whether certain populations are targeted by

abortion providers and whether better prenatal physical, mental, and social care improves infant outcomes and decreases abortion rates, especially among those who are most vulnerable.

The Ensuring Accurate and Complete Abortion Data Reporting Act of 2023[9] would amend title XIX of the Social Security Act and Public Health Service Act to improve the CDC's abortion reporting mechanisms by requiring states, as a condition of federal Medicaid payments for family planning services, to report streamlined variables in a timely manner.

The CDC should immediately end its collection of data on gender identity, which legitimizes the unscientific notion that men can become women (and vice versa) and encourages the phenomenon of ever-multiplying subjective identities.

FOOD AND DRUG ADMINISTRATION (FDA)

The FDA's mission includes ensuring the safety and efficacy of drugs, biological products, and medical devices.

Federal Laws That Shield Big Pharma from Competition. Because generics generally cost far less than brand-name drugs, consumers begin to save money as soon as a generic product comes on the market. The vast majority are very affordable with 93 percent of generic products costing $20 or less.

Savings would be even higher under proposals that prevent brand-name manufacturers from slowing down or impeding the entrance of generic products into the marketplace. Specifically, the FDA should prohibit pharmaceutical companies from purposely sitting on their legally available right to be the first to sell generic versions of their drugs. Additionally, Congress should create legal remedies for generic companies to obtain samples of brand-name products for their generic development efforts and should prohibit meritless "citizen petitions" submitted by manufacturers to delay approval of a generic competitor.[10]

Approval Process for Laboratory-Developed or Modified Medical Tests. Learning from the failed early COVID-19 testing experience, Congress and the FDA should focus on reforming laws and regulations governing medical tests, especially with respect to laboratory-developed tests.

Commercial tests are developed with the intention of being widely marketed, distributed, and used, while laboratory-developed tests are created with the intention of being used solely within one laboratory. A test developed by a lab in accordance with the protocols developed by another lab (non-commercial sharing) currently constitutes a "new" laboratory-developed test because the lab in which it will be used is different from the initial developing lab. To encourage interlaboratory collaboration and discourage duplicative test creation (and associated regulatory and logistical burdens), the FDA should introduce mechanisms through which laboratory-developed tests can easily be shared with other laboratories without the current regulatory burdens.[11]

The "laboratory-developed tests" category currently encompasses a range of possible tests, many of which would be characterized more appropriately as "laboratory-modified tests" because they are not truly novel tests but rather modified versions of existing tests. To avoid stifling innovation and access to medical care, the applicable statutes and regulations should be revised to facilitate greater access to such modified tests.[12]

Finally, the FDA has long held that it has regulatory authority over such tests, while others have argued that they should be considered clinical services regulated by the Centers for Medicare and Medicaid Services (CMS). The FDA currently has regulatory authority over in vitro diagnostics, and under the Clinical Laboratory Improvement Amendments (CLIA),[13] the CMS ensures that labs meet analytical validity standards for test methods. Congress, the FDA, and the CMS need to clarify and disentangle overlapping authorities over tests to eliminate regulatory confusion.[14]

Drug Shortages. The very thin profit margins and the regulatory burdens associated with generic drug manufacturing discourage inventory and capacity investments by manufacturers and contribute to drug shortages. HHS and the FDA should encourage more dependable generic drug manufacturing.

The FDA should expand its current pass/fail approach to drug facility inspections into a graded system that recognizes manufacturers that exceed minimum standards by investing in improving production reliability. The FDA should also add facility codes to drug packaging and construct a searchable database that cross-references product codes and facility codes. That would enable wholesalers and pharmacy benefit managers to identify and preference drugs manufactured at more reliable facilities, thus encouraging generic drug manufacturers to compete on reliability as well as on price.

For its part, HHS should exempt multi-source generic drugs from requirements to pay rebates to Medicaid and other federally funded health programs, as those provisions penalize new investments in expanding manufacturing capacity when supply is unable to meet demand.[15] Additionally, FDA and NIH should promote efficacy trials of new applications for generic drugs, which might include NIH funding such trials or conducting its own.

Abortion Pills. Abortion pills pose the single greatest threat to unborn children in a post-*Roe* world. The rate of chemical abortion in the U.S. has increased by more than 150 percent in the past decade; more than half of annual abortions in the U.S. are chemical rather than surgical.

The abortion pill regimen is typically a two-part process. The first pill, mifepristone, causes the death of the unborn child by cutting off the hormone progesterone, which is required to sustain a pregnancy. The second pill, misoprostol, causes contractions to induce a delivery of the dead child and uterine contents, usually into a toilet at home. The abortion-pill regimen is currently approved for up to 70 days

(10 weeks) into pregnancy and before Biden was subject to a heightened safety restriction called a Risk Evaluation and Mitigation Strategy (REMS) that requires an in-person visit with a physician who can check for dangerous contraindications such as ectopic pregnancies and can advise the mother seeking an abortion of the risks of chemical abortion, including hemorrhaging, and what to do in such circumstances. Chemical abortion has been found to have a complication rate four times higher than that of surgical abortion.

Since its approval more than 20 years ago, mifepristone has been associated with 26 deaths of pregnant mothers, over a thousand hospitalizations, and thousands more adverse events, but that number does not account for all complications. Of course, this does not count the hundreds of thousands to millions of babies whose lives have been unjustly taken through chemical abortion. FDA should therefore:

- **Reverse its approval of chemical abortion drugs because the politicized approval process was illegal from the start.** The FDA failed to abide by its legal obligations to protect the health, safety, and welfare of girls and women. It never studied the safety of the drugs under the labeled conditions of use, ignored the potential impacts of the hormone-blocking regimen on the developing bodies of adolescent girls, disregarded the substantial evidence that chemical abortion drugs cause more complications than surgical abortions, and eliminated necessary safeguards for pregnant girls and women who undergo this dangerous drug regimen. Furthermore, at no point in the past two decades has the FDA ever acknowledged or addressed federal laws that prohibit the distribution of abortion drugs by postal mail; to the contrary, the FDA has permitted and actively encouraged such activity.

  Now that the Supreme Court has acknowledged that the Constitution contains no right to an abortion, the FDA is ethically and legally obliged to revisit and withdraw its initial approval, which was premised on pregnancy being an "illness" and abortion being "therapeutically" effective at treating this "illness." The FDA is statutorily charged with guaranteeing the safety and efficacy of drugs and therefore should withdraw this drug that is proven to be dangerous to women and *by definition* fatally unsafe for unborn children.

As an interim step, the FDA should immediately restore the REMS by removing the in-person dispensing requirement to eliminate dangerous tele-abortion and abortion-by-mail distribution.

Mail-Order Abortions. Allowing mail-order abortions is a gift to the abortion industry that allows it to expand far beyond brick-and-mortar clinics and into

pro-life states that are trying to protect women, girls, and unborn children from abortion. The FDA should therefore:

- **Reinstate earlier safety protocols for Mifeprex that were mostly eliminated in 2016 and apply these protocols to any generic version of mifepristone.** A bare-minimum policy of limiting abortion pills to the pre-2016 policy of 49 days gestation, returning to the pre-2021 in-person dispensing requirement, and returning to requiring prescribers to report all serious adverse events, not just deaths, to the drug sponsor would increase women's health and safety.

- **Address weaknesses in the current FAERS (FDA Adverse Events Reporting System).** The Administration and policymakers should ensure that health care workers, particularly those in hospitals and emergency rooms, report abortion pill complications. Women who experience complications from abortion pills typically go to an emergency room, not to the abortion pill prescriber, so putting the onus of reporting on the prescriber who typically has no idea that a complication has occurred means that the FAERS is seriously undercounting adverse events. Submitting an adverse event to the database should be a quick and efficient process for busy health care practitioners. Currently, providers report that the process is difficult and convoluted.

- **Implement a policy of transparency about inspections of the abortion pill's sponsors, Danco and GenBioPro, as well as facilities that manufacture the pills.** The FDA should respond to congressional requests and Freedom of Information Act (FOIA) requests about inspections, compliance, and post-marketing safety in a timely manner.

- **Stop promoting or approving mail-order abortions in violation of long-standing federal laws that prohibit the mailing and interstate carriage of abortion drugs.**[16]

Vaccine Importation. Thousands of Americans of faith and conscience wish to receive various childhood vaccinations for themselves and their families but are not allowed to receive vaccines that are derived through or tested on aborted fetal cells. For example, the chickenpox, Hepatitis, and MMR vaccines in the U.S. are all linked to abortion in this way. There are ethically derived alternatives abroad that have been used safely there for decades, but the FDA makes it exceedingly difficult for Americans to import them.

In January 2021, the HHS Office for Civil Rights (OCR) and the FDA jointly announced that HHS was required by the Religious Freedom Restoration Act

(RFRA)[17] to allow bulk importation by doctors of certain Japanese-made vaccines to accommodate religious needs of patients, but the Biden FDA unlawfully revoked this waiver. The FDA should restore the waiver to comply with RFRA and for the obvious public health benefits of increased childhood vaccination by families seeking ethically derived alternatives.

To avoid future moral coercion of the sort experienced with the COVID-19 vaccines, the FDA and NIH should require the development of drugs and biologics that are free from moral taint and switch to cell lines that are not derived from aborted fetal cell lines or aborted baby body parts.

Conflicts of Interest. A 2018 report in *Science* found that more than two-thirds of FDA reviewers later ended up at the same companies whose products they had been reviewing while they were working for the government.[18] This revolving door is one mechanism by which pharmaceutical companies capture the agencies that regulate them. The FDA should impose a lengthy cooling off period for reviewers, preventing them from working for companies they regulated.

In 1997, the FDA relaxed regulations to permit broadcast drug advertisements, after which Big Pharma began routine direct-to-consumer advertising, making the United States and New Zealand the only countries where such practices are legal. Following the 1997 changes, pharma became the largest advertiser for all major media organizations. This buys considerable influence in the newsroom—whether media companies acknowledge this or not—and distorts independent reporting on public health issues. The FDA or Congress should regulate where and how paid advertising is used by pharmaceutical companies more stringently, especially on media outlets.

NATIONAL INSTITUTES OF HEALTH (NIH)

The National Institutes of Health (NIH) is the world's largest biomedical research agency and is made up of 27 different components called Institutes and Centers. Despite its popular image as a benign science agency, NIH was responsible for paying for research in aborted baby body parts, human animal chimera experiments, and gain-of-function viral research that may have been responsible for COVID-19.

Bioethics Reform. Research using fetal tissue obtained from elective abortions is immoral and obsolete. Research using human embryonic stem cells also involves the destruction of human life and should not be subsidized with taxpayer dollars. Good science and life-affirming, ethical research are not mutually exclusive. In fact, ethically derived sources such as discarded surgical tissue and adult stem cells (made pluripotent), not tissue obtained from elective abortions, have contributed the most successful treatments for a variety of ailments.

Congress authorized HHS to choose not to fund extramural abortion-derived fetal tissue research that fails ethics advisory board review, and in 2019, the

Trump Administration's HHS chose that course. Subsequently, however, the Biden Administration restored unrestricted funding of abortion-derived fetal tissue research. HHS should:

- **Promptly restore the ethics advisory committee to oversee abortion-derived fetal tissue research, and Congress should prohibit such research altogether.**

- **End intramural research projects using tissue from aborted children within the NIH, which should end its human embryonic stem cell registry.**

- **Aggressively implement a plan to pursue and fund ethical alternative methods of research in order to ensure that abortion and embryo-destructive related research, cell lines, and other testing methods become both fully obsolete and ethically unthinkable.**

In addition, the Administration should reconvene a new National Council on Bioethics (NCB) to discuss new and emerging areas of ethical concern, to assess whether the ends justify the means when it comes to the promise of therapies and cures, and to establish what limiting principles should guide research and health policy. Because the male–female dyad is essential to human nature and because every child has a right to a mother and father, three-parent embryo creation and human cloning research should be banned. A new NCB should convene leading experts to examine these issues and provide policy recommendations for the new frontier of bioethical questions that our country will have to address in the coming years.

Finally, HHS should create and promote a research agenda that supports pro-life policies and explores the harms, both mental and physical, that abortion has wrought on women and girls.

Conflicts of Interest. NIH maintains inappropriate industry ties that create serious conflicts of interest. In 2018, it was revealed that a $100 million NIH study on the benefits of moderate drinking was funded by the beer and liquor industry.[19] More recently, the National Institute of Allergy and Infectious Diseases (NIAID), Anthony Fauci's division of the NIH, owns half of the patent for the Moderna COVID-19 vaccine, among thousands of other pharma patents.[20] Rather than providing grants to university-based investigators to run the clinical trials on their own Moderna vaccine, the NIH conducted this research internally—a clear conflict of interest. The NIAID will earn millions from this vaccine's revenue with several NIH employees (and their heirs) personally receiving up to $150,000 annually from Moderna vaccine sales.[21]

In May 2022, documents obtained pursuant to a FOIA request revealed that NIH Director Francis Collins, NAIAD Director Anthony Fauci, and Fauci's Deputy Director, Clifford Lane, all received royalties from pharmaceutical companies between 2009 and 2014.[22] Nonprofit watchdog Open the Books estimates that from 2010 to 2020, third parties paid more than $350 million in royalties to NIH and its scientists, who are credited as coinventors. Most problematically, in the years when they received payments, Collins, Fauci, and Lane were NIH administrators, not researchers, with no plausible claim to be scientific co-discoverers.

Most of the world's other advanced science countries have stricter prohibitions on such conflicts, which helps to explain why the most significant studies on COVID treatments, on natural immunity, and on vaccine efficacy have come mostly from outside the U.S.

Funding for scientific research should not be controlled by a small group of highly paid and unaccountable insiders at the NIH, many of whom stay in power for decades. The NIH monopoly on directing research should be broken. Term limits should be imposed on top career leaders at the NIH, and Congress should consider block granting NIH's grants budget to states to fund their own scientific research. Nothing in this system would prevent several states from partnering to co-fund large research projects that require greater resources or impact larger regions. Likewise, the establishment of funding for scientific research at the state level does not preclude more modest federal funding through the National Institutes of Health: The two models are not mutually exclusive.

The CDC and NIH Foundations, whose boards are populated with pharmaceutical company executives, need to be decommissioned. Private donations to these foundations—a majority of them from pharmaceutical companies—should not be permitted to influence government decisions about research funding or public health policy.

Woke Policies. Under Francis Collins, NIH became so focused on the #MeToo movement that it refused to sponsor scientific conferences unless there were a certain number of women panelists, which violates federal civil rights law against sex discrimination. This quota practice should be ended, and the NIH Office of Equity, Diversity, and Inclusion, which pushes such unlawful actions, should be abolished.

NIH has been at the forefront in pushing junk gender science. Instead, it should fund studies into the short-term and long-term negative effects of cross-sex interventions, including "affirmation," puberty blockers, cross-sex hormones and surgeries, and the likelihood of desistence if young people are given counseling that does not include medical or social interventions.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

With the goal of being a societal safety net, Medicare and Medicaid touch more American lives than does any other federal program. While they help many, they

operate as runaway entitlements that stifle medical innovation, encourage fraud, and impede cost containment, in addition to which their fiscal future is in peril.

Both programs should be managed so that the individuals enrolled are empowered to make decisions for themselves and have quality options with affordable prices driven by competition and innovation. Providers who participate should retain (or have restored) the freedom to practice medicine and take care of their patients according to their patients' unique needs.

Medicare. Medicare should be reformed according to four goals and principles:

- **Increase Medicare beneficiaries' control of their health care.** Patients are best positioned to determine the value of health care services, working with their health care providers. They also benefit from increased choice of doctors, hospitals, and insurance plans. Access to reliable information with respect to physicians, hospitals, and insurers is therefore essential.

- **Reduce regulatory burdens on doctors.** Doctors must be free to focus on treating patients first, not entering codes on computers, and should not be tempted to change their medical judgment based on arbitrary or illogical reimbursement incentives.

- **Ensure sustainability and value for beneficiaries and taxpayers.** Prices are best for patients when determined by economic value rather than political power and when they are known in advance of the receipt of services. Government's use of non-market-based methods to determine reimbursement leads to overspending on low-value services and products and underpayment for high-value services and products, stifles beneficial innovation, and because of Medicare's size distorts payments throughout the health care system. Intermediate entities that can manage financial risk and ensure quality of care are important in transitioning to value-based care within the Medicare program.

- **Reduce waste, fraud, and abuse,** including through the use of artificial intelligence for their detection.

Regulatory Reforms. Medicare regulations restrict choice of coverage and care. The next Administration should reintroduce and restore regulations and demonstrations from the Trump Administration that were withdrawn, weakened, or never finalized by the Biden Administration, including:

- The Medicare Coverage of Innovative Technologies (MCIT) rule;

- The Risk Adjustment Data Validation (RADV) rule;

- The Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) demonstration; and

- The Global and Professional Direct Contracting (GPDC, rebranded as the Accountable Care Organization Realizing Equity, Access, and Community Health or ACO REACH) model.

Additionally, regulations should advance site neutrality by eliminating the inpatient-only list and expanding the ambulatory surgical center covered procedures list. Medicare generally pays more for inpatient hospital procedures and less for the same procedures performed in an outpatient setting. Whether a medical service is delivered in a physician's office, a clinic, or a hospital setting, the Medicare payment for that service should be the same. CMS should expand the application of site-neutral payment options to more settings. Such a policy would level the playing field among providers and remove the financial disabilities for medical professionals who would compete with hospital systems.[23]

Finally, HHS needs to restore and enhance conscience protection regulations that allow medical practitioners to participate in federal health care programs without being compelled to provide sex changes or similar services.

LEGISLATIVE PROPOSALS

- **Remove restrictions on physician-owned hospitals.** The Affordable Care Act (ACA)[24] imposed restrictions prohibiting Medicare from reimbursing physician-owned and specialty hospitals. The current restrictions do little more than serve the special interests of large hospital systems and undercut consumer choice of high-quality, specialty care. These restrictions should be removed so that physician-owned hospitals can compete with other hospitals in serving Medicare patients.[25]

- **Encourage more direct competition between Medicare Advantage and private plans.** Medicare Advantage (MA), a system of competing private health plans, is the major alternative to traditional Medicare for America's large and growing cohort of seniors. The program provides beneficiaries with a wide range of competitive health plan choices—a richer set of benefits than traditional Medicare provides and at a reasonable cost. Equally as important, the MA program has been registering consistently high marks for superior performance in delivering high-quality care. Critical reforms are still needed to strengthen and improve the program for the future. Specifically:

1. Make Medicare Advantage the default enrollment option.

2. Give beneficiaries direct control of how they spend Medicare dollars.

3. Remove burdensome policies that micromanage MA plans.

4. Replace the complex formula-based payment model with a competitive bidding model.

5. Reconfigure the current risk adjustment model.

6. Remove restrictions on key benefits and services, including those related to prescription drugs, hospice care, and medical savings account plans.[26]

Legacy Medicare Reform. Legislation reforming legacy (non-MA) Medicare should:

- **Base payments on the health status of the patient or intensity of the service rather than where the patient happens to receive that service.**

- **Replace the bureaucrat-driven fee-for-service system with value-based payments to empower patients to find the care that best serves their needs.**

- **Codify price transparency regulations.**

- **Restructure 340B drug subsidies[27] toward beneficiaries rather than hospitals.**

- **Repeal harmful health policies enacted under the Obama and Biden Administrations such as the Medicare Shared Savings Program[28] and Inflation Reduction Act.[29]**

Medicare Part D Reform. The Inflation Reduction Act (IRA) created a drug price negotiation program in Medicare that replaced the existing private-sector negotiations in Part D with government price controls for prescription drugs. These government price controls will limit access to medications and reduce patient access to new medication.

This "negotiation" program should be repealed, and reforms in Part D that will have meaningful impact for seniors should be pursued. Other reforms should include eliminating the coverage gap in Part D, reducing the government share in

the catastrophic tier, and requiring manufacturers to bear a larger share. Until the IRA is repealed, an Administration that is required to implement it must do so in a way that is prudent with its authority, minimizing the harmful effects of the law's policies and avoiding even worse unintended consequences.[30]

Medicaid. Over the past 45 years, Medicaid and the health safety net have evolved into a cumbersome, complicated, and unaffordable burden on nearly every state. The program is failing some of the most vulnerable patients; is a prime target for waste, fraud, and abuse; and is consuming more of state and federal budgets. The dramatic increase in Medicaid expenditures is due in large part to the ACA (Obamacare), which mandates that states must expand their Medicaid eligibility standards to include all individuals at or below 138 percent of the federal poverty level (FPL), and the public health emergency, which has prohibited states from performing basic eligibility reviews.

The overlap of available benefits among the various health agencies has led to a complex, confusing system that is nearly impossible to navigate—even for recipients. Recipients are often faced with a "welfare cliff" of benefit losses as they earn above a certain amount, which is contrary to the fundamental purpose of empowering individuals to achieve economic independence. Benefits increasingly involve nonmedical services such as air conditioning and housing, many of which are already handled by departments other than HHS.

Improper payments within Medicaid are higher than those of any other federal program. These payments are evidence of the inappropriateness of Medicaid's expansion, which, stemming largely from public health emergency maintenance of effort (MOE) requirements and the Affordable Care Act, has crowded out the primary targets of these programs: those who are most in need.

True health care reform cannot be accomplished in a bureaucratic silo or only through Medicaid and health safety net programs. Reform of the tax code is also essential to genuine, effective reform of our health care system. All components of the health care system should be part of the reform efforts, and it is imperative that the system be modified to assist states with their current programs. Therefore, the next Administration should:

- **Reform financing.** Allow states to have a more flexible, accountable, predictable, transparent, and efficient financing mechanism to deliver medical services. This system should include a more balanced or blended match rate, block grants, aggregate caps, or per capita caps. Any financial system should be designed to encourage and incentivize innovation and the efficient delivery of health care services. Federal and state financial participation in the Medicaid program should be rational, predictable, and reasonable. It should also incentivize states to save money and improve the quality of health care.

- **Direct dollars to beneficiaries more effectively and responsibly.** The current funding structure for the Medicaid program rewards expansions, lacks transparency, and promotes financing gimmicks. CMS should:

    1. End state financing loopholes.

    2. Reform payments to hospitals for uncompensated care.

    3. Replace the enhanced match rate with a fairer and more rational match rate.

    4. Restructure basic financing and put the program on a more fiscally predictable budget (which should include reform of Disproportionate Share Hospital payments to hospitals).[31]

- **Strengthen program integrity.** Make program integrity a top priority and the responsibility of the states. To protect the taxpayers' investment:

    1. **Incentivize states.** An enhanced contingency fee should be paid to states that successfully increase their efforts to decrease waste, fraud, and abuse. The current system's IT development 90/10 matching rate should be allowed for improvements in states' current fraud and abuse and eligibility systems. Innovative programs that show a positive return on investment for both the state and federal governments should be allowed without the onerous waiver process.

    2. **Improve Medicaid eligibility standards to protect those in need.** As Medicaid enrollment continues to climb, it is imperative that there are appropriate and accurate eligibility standards to ensure that the program remains focused on serving those who are in need. To this end, CMS should:

        a. Hold states accountable for improper eligibility determinations.
        b. Require more robust eligibility determinations.
        c. Strengthen asset test determinations within Medicaid.[32]

    3. **Conduct oversight and reform of managed care.**[33]

- **Incentivize personal responsibility.** CMS should allow states to ensure that Medicaid recipients have a stake in their personal health care and a say in decisions related to the Medicaid program. Personal responsibility

and consumer choice for Medicaid recipients must go together as standard components of the safety net, especially for able-bodied recipients. Medicaid recipients, like the rest of Americans, should be given both the freedom to choose their health plans and the responsibility to contribute to their health care costs at a level that is appropriate to protect the taxpayer.

- **Add work requirements and match Medicaid benefits to beneficiary needs.** Because Medicaid serves a broad and diverse group of individuals, it should be flexible enough to accommodate different designs for different groups. For example, CMS should launch a robust "personal option" to allow families to use Medicaid dollars to secure coverage outside of the Medicaid program. CMS should also:

  1. Clarify that states have the ability to adopt work incentives for able-bodied individuals (similar to what is required in other welfare programs) and the ability to broaden the application of targeted premiums and cost sharing to higher-income enrollees.

  2. Add targeted time limits or lifetime caps on benefits to disincentivize permanent dependence.[34]

- **Allow private health insurance.** Congress should allow states the option of contributing to a private insurance benefit for all members of the family in a flexible account that rewards healthy behaviors. This reform should also allow catastrophic coverage combined with an account similar to a health savings account (HSA) for the direct purchase of health care and payment of cost sharing for most of the population.

- **Increase flexible benefit redesign without waivers.** CMS should add flexibility to eliminate obsolete mandatory and optional benefit requirements and, for able-bodied recipients, eliminate benefit mandates that exceed those in the private market. This should include flexibility to redesign eligibility, financing, and service delivery of long-term care to serve the most vulnerable and truly needy and eliminate middle-income to upper-income Medicaid recipients.

- **Eliminate current waiver and state plan processes.** CMS should allow providers to make payment reforms without cumbersome waivers or state plan amendment processes where possible. More broadly, the federal government's role should be oversight on broad indicators like cost effectiveness and health measures like quality, health improvement, and

wellness and should give the balance of responsibility for Medicaid program management to states. This reform would include adding Section 1115[35] waiver requirements in some cases (such as imposing work requirements for able-bodied adults) while rescinding requirements in others (such as non–health care benefits and services related to climate change).

AFFORDABLE CARE ACT AND PRIVATE HEALTH INSURANCE

- **Remove barriers to direct primary care.** Direct primary care (DPC) is an innovative health care delivery model in which doctors contract directly with patients for their care on a subscription basis regardless of how or where the care is provided. The DPC model is improving patient access, driving higher quality and lower cost, and strengthening the doctor–patient relationship. DPC has faced many challenges from government policymakers, including overly exuberant attempts at regulation and misclassification. Changes should clarify that DPC's fixed fee for care does not constitute insurance in the context of health savings accounts.[36]

- **Revisit the No Surprises Act on surprise medical billing**. The No Surprises Act[37] protected consumers against balance bills, but it also established a deeply flawed system for resolving payment disputes between insurers and providers. This government-mandated dispute resolution process has sown confusion among arbiters and regulators as judges have sought to ascertain its meaning. The No Surprises Act should scrap the dispute resolution process in favor of a truth-in-advertising approach that will protect consumers and free doctors, insurers, and arbiters from confused and conflicting standards for resolving disputes that the disputing parties can best resolve themselves.[38]

- **Facilitate the development of shared savings and reference pricing plan options.** Under traditional insurance, patients who choose lower-cost care do not benefit financially from that choice. Barriers to rewarding patients for cost-saving decisions should be removed. CMS should ensure that shared savings and reference pricing models that reward consumers are permitted.

- **Separate the subsidized ACA exchange market from the non-subsidized insurance market.** The Affordable Care Act has made insurance more expensive and less competitive, and the ACA subsidy scheme simply masks these impacts. To make health insurance coverage more affordable for those who are without government subsidies, CMS should develop a plan to separate the non-subsidized insurance market

from the subsidized market, giving the non-subsidized market regulatory relief from the costly ACA regulatory mandates.[39]

- **Strengthen hospital price transparency.** In 2020, CMS completed its rule to require hospitals to post the prices of common hospital procedures.[40] Future updates of these rules should focus on including quality measures. Combined with the shared savings models and other consumer tools, these efforts could deliver considerable savings for consumers.[41]

Center for Consumer Information and Insurance Oversight (CCIIO). CMS also plays an outsized role in overseeing the Obamacare exchanges, including managing Healthcare.gov, through the Center for Consumer Information and Insurance Oversight (CCIIO). While Obamacare limits plan options, CCIIO has been overly prescriptive in dictating what benefits and types of health plans may participate in the exchanges, thereby actually stifling market innovation and driving up costs.

Congress should build on the Trump Administration's efforts to expand choices for small businesses and workers, both in and out of the exchanges, by codifying an expansion of association health plans, short-term health plans, and health reimbursement arrangements (including individual coverage HRAs). CCIIO should also work with the Treasury Department and the Office of Management and Budget (OMB) to give consumers more flexibility with their health care dollars through expanded access to health savings accounts.

EMERGENCY PREPAREDNESS

- **Expand the scope of practice of low-complexity and moderate-complexity clinical laboratories.** During the COVID-19 pandemic, allowing laboratories greater regulatory flexibility regarding CLIA requirements increased access to testing. However, the need for regulatory flexibility is not limited to emergency situations. Ongoing innovations in medical care will continue to drive demand for clinical testing and new tests. One way that increasing demand for other medical services has been accommodated is by revising restrictions on scope of practice to enable providers to practice at the so-called top of their license. CMS should similarly revise CLIA rules regarding scope of practice for clinical laboratories and testing personnel.[42]

- **Create CLIA-certification-equivalent pathways for non-clinical laboratories and researchers.** The COVID-19 pandemic revealed that the U.S. needs to leverage the expertise of non-clinical laboratories and researchers in order to bolster clinical testing capacity. To accomplish this,

CMS should create pathways for granting non-clinical laboratories and their testing personnel CLIA certification equivalency. Non-clinical researchers already demonstrate their technical expertise through online training and certification programs. CMS should build on that existing framework so that those laboratories and personnel can similarly demonstrate their clinical testing capabilities.[43]

LIFE, CONSCIENCE, AND BODILY INTEGRITY

- **Prohibit abortion travel funding.** Providing funding for abortions increases the number of abortions and violates the conscience and religious freedom rights of Americans who object to subsidizing the taking of life. The Hyde Amendment[44] has long prohibited the use of HHS funds for elective abortions, but an August 2022 Biden executive order[45] pressed the HHS Secretary to use his authority under Section 1115 demonstrations to waive certain provisions of the law in order to use taxpayer funds to achieve the Administration's goal of helping women to travel out of state to obtain abortions. Moreover, the Department of Justice Office of Legal Counsel (DOJ OLC) issued a politicized legal opinion declaring, for the first time in the history of Hyde, that this action did not violate the Hyde Amendment and that Hyde applies only to the performance of the abortion itself in violation of the plainly broad language that Congress used.

  Two of the first actions of a pro-life Administration should be for HHS to withdraw the Medicaid guidance (and any Section 1115 waivers issued thereunder) and for DOJ OLC to withdraw and disavow its interpretation of the Hyde Amendment.

- **Prohibit Planned Parenthood from receiving Medicaid funds.** During the 2020–2021 reporting period, Planned Parenthood performed more than 383,000 abortions.[46] The national organization reported more than $133 million in excess revenue[47] and more than $2.1 billion in net assets.[48] During this same year, Planned Parenthood reports that its affiliates received more than $633 million in government funding and more than $579 million in private contributions.[49] Planned Parenthood affiliates face accusations of waste, abuse and potential fraud with taxpayer dollars, failure to report the sexual abuse of minor girls, and allegations of profiting from the sale of organs from aborted babies.

  Policymakers should end taxpayer funding of Planned Parenthood and all other abortion providers and redirect funding to health centers that provide real health care for women. The bulk of federal funding for Planned

Parenthood comes through the Medicaid program. HHS should take two actions to limit this funding:

1. Issue guidance reemphasizing that states are free to defund Planned Parenthood in their state Medicaid plans.

2. Propose rulemaking to interpret the Medicaid statute to disqualify providers of elective abortion from the Medicaid program.

Congress should pass the Protecting Life and Taxpayers Act,[50] which would accomplish the goal of defunding abortion providers such as Planned Parenthood.

CMS should resolve pending Section 1115 waivers from Idaho, South Carolina, and Tennessee, which, like Texas in January 2022, are seeking both to prohibit abortion providers from participating in state-run Medicaid programs and to work with other states to do the same. Abortion is not health care, and states should be free to devise and implement programs that prioritize qualified providers that are not entangled with the abortion industry.

- **Withdraw Medicaid funds for states that require abortion insurance or that discriminate in violation of the Weldon Amendment.** The Weldon Amendment[51] declares that no HHS funding may go to a state or local government that discriminates against pro-life health entities or insurers. In blatant violation of this law, seven states require abortion coverage in private health insurance plans, and HHS continues to fund those states. HHS under President Trump disallowed $200 million in Medicaid funding from California because of the state's flouting of the law, but the Biden Administration restored it.

  HHS/CMS should withdraw appropriated funding, up to and including 10 percent of Medicaid funds, from states that require abortion insurance coverage. DOJ should commit to litigating the defense of those funding decisions promptly to the Supreme Court in order to maximize HHS's ability to withdraw funds from entities that violate the Weldon Amendment.

  Additionally, California has announced that it will discriminate against pharmacies that do not carry chemical abortion drugs *outside* of California. California's discrimination takes the form of cutting state contracts with such pharmacies and clearly violates the Weldon Amendment. The violation should likewise face the penalties discussed above.

- **Rewrite the ACA abortion separate payment regulation.** Section 1303 of Obamacare requires that insurers collect a separate payment for certain abortion coverage in qualified health plans that are approved to be sold on exchanges and that they keep those separate payments in separate accounts that are used only to pay for elective abortion services. Neither the letter nor the spirit of the law was enforced under President Obama, and a Trump-era regulation sought to correct this problem. The Biden HHS rescinded this regulation to allow insurance companies once again—contrary to the law—to collect combined payments for what are clearly required to be separate payments for elective abortion coverage. "Separate" does not mean "together."

  HHS should reinstate a Trump Administration regulation and enforce what the plain text of Section 1303 requires. That regulation should be further improved by requiring CMS to ensure that consumers pay truly separate charges for abortion coverage.

- **Audit Hyde Amendment compliance.** HHS should undertake a full audit to determine compliance or noncompliance with the Hyde amendment and similar funding restrictions in HHS programs. This audit should include a full review of the Biden Administration's post-*Dobbs* executive actions to promote abortion. It should also encompass a review of Medicaid managed care plans in pro-abortion states.

- **Reverse distorted pro-abortion "interpretations" added to the Emergency Medical Treatment and Active Labor Act.** The Emergency Medical Treatment and Active Labor Act (EMTALA)[52] prohibits hospitals that receive Medicare funds from "dumping" emergency patients who cannot pay by sending them to other hospitals. It also mandates that hospitals stabilize pregnant women and explicitly protects unborn children. Hospitals or physicians found to be in violation of the statute could lose all of their federal health funding—Medicare, Medicaid, CHIP, and other funds—and face civil penalties of up to nearly $120,000.

  In July 2022, HHS/CMS released guidance mandating that EMTALA-covered hospitals and the physicians who work there must perform abortions, to include completing chemical abortions even when the child might still be alive. The guidance also declared that EMTALA would protect physicians and hospitals that perform abortions in violation of state law if they deem those abortions necessary to stabilize the women's health. This novel interpretation of EMTALA is baseless. EMTALA requires

no abortions, preempts no pro-life state laws, and explicitly requires stabilization of the unborn child.

HHS should rescind the guidance and end CMS and state agency investigations into cases of alleged refusals to perform abortions. DOJ should agree to eliminate existing injunctions against pro-life states, withdraw its enforcement lawsuits, and in lawsuits against CMS on the guidance agree to injunctions against CMS and withdraw appeals of injunctions.

- **Reissue a stronger transgender national coverage determination.** CMS should repromulgate its 2016 decision that CMS could not issue a National Coverage Determination (NCD) regarding "gender reassignment surgery" for Medicare beneficiaries. In doing so, CMS should acknowledge the growing body of evidence that such interventions are dangerous and acknowledge that there is insufficient scientific evidence to support such coverage in state plans.

- **Enforce EMTALA.** The undeniable reality of abortion is that it does do not always result in a dead baby, and these born-alive babies are left to die. HHS should use EMTALA and Section 504 of the Rehabilitation Act,[53] which prohibits disability discrimination, to investigate instances of infants born alive and left untreated in covered hospitals. CMS, OCR, and OIG should be required to follow through on these investigations with specific enforcement actions.

  HHS should revive a Trump Administration proposed regulation, "Special Responsibilities of Medicare Hospitals in Emergency Cases and Discrimination on the Basis of Disability in Critical Health and Human Service Programs or Activities,"[54] to achieve this end. In addition, Congress should pass the Born-Alive Abortion Survivors Protection Act[55] to require that proper medical care be given to infants who survive an abortion and to establish criminal consequences for practitioners who fail to provide such care.

- **Permanently codify both the Hyde family of amendments and the protections provided by the Weldon Amendment.** Congress can accomplish this through legislation such as the No Taxpayer Funding for Abortion and Abortion Insurance Full Disclosure Act[56] (Hyde) and the Conscience Protection Act[57] (Weldon).

Radical Redefinition of Sex. On August 4, 2022, HHS published a proposed rule entitled "Nondiscrimination in Health Programs and Activities."[58] This rule addresses nondiscrimination provisions of the Affordable Care Act, known as Section 1557, which is enforced by the Office for Civil Rights and the Centers for Medicare and Medicaid Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, age, disability, and sex in covered health programs or activities.

Under the proposed rule, sex is redefined: "Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity."[59] In other words, the department proposes to interpret Section 1557 as if it created special privileges for new classes of people, defined in ways that are highly ideological and unscientific.

The redefinition of sex to cover gender identity and sexual orientation and pregnancy to cover abortion should be reversed in all HHS and CMS programs as was done under the Trump Administration. This includes the Children's Health Insurance Program (CHIP). Low-income families who rely on CHIP should not be coerced, pressured, or otherwise encouraged to embrace this ideologically motivated sexualization of their children.

However, while the Biden Administration's Section 1557 regulation should be altered and corrected, the lactation room requirements added in the regulation should either be consistently included in any upcoming Section 1557 rulemaking or be proposed in a new individual rule.

COVID-19 Vaccination and Mask Requirements. Health care workers were praised for their self-sacrifice in caring for sick patients at the beginning of the COVID-19 pandemic, but then they were fired if they objected to receiving COVID-19 vaccines with or without complying with onerous masking requirements and regardless of whether they already had the virus and had gained natural immunity. With the disease being endemic and constantly mutating, vaccines and universal masking in health care facilities do not have appreciable benefits in reducing COVID-19 transmission throughout the community. Moreover, more recent COVID strains pose fewer health risks than the earlier strains, and the pandemic has been declared to be at an end. CMS should:

- Announce nonenforcement of the Biden Administration's COVID-19 vaccination mandate on Medicaid and Medicare hospitals.
- Revoke corresponding guidance and regulations.
- Refrain from imposing general COVID-19 mask mandates on health care facilities or personnel.

- Pay damages to all medical professionals who were dismissed directly because of the CMS vaccine mandate.

ADMINISTRATION FOR CHILDREN AND FAMILIES (ACF)

TANF. The Temporary Assistance for Needy Families (TANF) program is a federal block grant that gives states significant flexibility to fund a broad array of programs aimed at helping low-income families break the cycle of poverty and achieve economic self-sufficiency. States use TANF to fund monthly cash assistance payments to low-income families with children as well as a wide range of services that include work activities, work supports and supportive services, childcare, administration and systems, tax credits, pre-K/Head Start, child welfare, and other services.

The TANF program serves 1.8 million individuals. Since 1996, when the program was reformed, federal TANF outlays have been $16.5 billion. The state match is $14.9 billion, bringing the total state and federal TANF investment to $31.4 billion.

The TANF statute requires that states engage 50 percent of single-parent families in work for at least 30 hours a week (20 hours a week for single parents with children under age six, though states have the option to waive the requirement for families with children under the age of six, and most do). States also have 90 percent work requirements for two-parent families to engage in work for 35 hours per week. Because of the "Caseload Reduction Credit," states' work engagement targets are reduced if their assistance caseloads have fallen since 2005. As a result, 21 states had a work engagement target of zero percent in 2017.

Generally, states apply their work requirement only to beneficiaries receiving basic assistance, who account for 22.3 percent of TANF outlays. The Trump Administration proposed a Supplemental Nutrition Assistance Program (SNAP) rule to "increase program integrity and reduce fraud, waste, and abuse" that would have prevented an individual from qualifying for SNAP simply because he or she received a pamphlet from the TANF program.[60] This rule defined non-cash benefits as those that are worth at least $50 a month and received for at least six months. The tenets of this rule should be applied to the TANF program as well. This definitional change would apply the TANF work requirements to any noncash benefit worth $50 a month and received for six consecutive months.

To increase transparency, HHS should clarify how states, in their quarterly and annual reports, ought to track and audit the outcomes from how they spend TANF funds to meet the TANF program's four statutory purposes.

Additionally, TANF priorities are not implemented in an equally weighted way. Marriage, healthy family formation, and delaying sex to prevent pregnancy are virtually ignored in terms of priorities, yet these goals can reverse the cycle of poverty in meaningful ways. CMS should require explicit measurement of these goals.

Teen Pregnancy Prevention (TPP) and Personal Responsibility Education Program (PREP). TPP is operated by the Office of Population Affairs in the Office of the Assistant Secretary for Health; PREP is operated by the ACF Office of Planning, Research, and Evaluation. Both programs should ensure that there is better reporting of subgrantees and referral lists so that they do not promote abortion or high-risk sexual behavior among adolescents. CMS should ensure that Sexual Risk Avoidance (SRA) proponents receive these grants and are given every opportunity to prove their effectiveness. SRA programs, both at ACF and at OASH and both discretionary and mandatory, should be equal in funding and emphasis. Qualitative research should be conducted on both types of programs to ensure continuous improvement.

In addition, certain provisions should be employed so that these programs do not serve as advocacy tools to promote sex, promote prostitution, or provide a funnel effect for abortion facilities and school field trips to clinics, or for similar purposes. Parent involvement and parent–child communication should be encouraged and be a part of any funded project. Risk avoidance should be prioritized, and any program that submits a proposal that promotes risk rather than health should not be eligible for funding.

Site visits should be revamped to ensure adherence to these optimal health metrics, and a cost analysis of programming as compared to students served should be a metric in funding (taking into account that in certain cases, intensive programs will serve fewer students and can have more positive results). These same parameters should apply to sex education programs at ACF. Any lists with "approved curriculum" or so-called evidence-based lists should be abolished; HHS should not create a monopoly of curriculum, adding to the profit of certain publishers. Furthermore, lists created in the past have given priority to sex-promotion textbooks. HHS should create a list of criteria for evaluating the sort of curriculum that should be selected for any sex education grant programs, both at OASH and at ACF, with the aim of promoting optimal health and adhering to the legislative language of each program.

Adoption Reform. There are roughly 400,000 children across the nation on the waiting list for foster care and 100,000 awaiting adoptive families, and the opioid/fentanyl crisis is putting more at risk every day. Unfortunately, many of the faith-based adoption agencies that serve these children are under threat from lawsuits, or else their licenses and contracts have been halted because they cannot in good conscience place children in every household due to their religious belief that a child should have a married mother and father.

HHS, through ACF and the Assistant Secretary for Financial Resources (ASFR), should repeal the unnecessary 2016 regulation[61] that imposes nonstatutory sexual orientation and gender identity nondiscrimination conditions on agency grants and return to the policy of maximizing the options for placing vulnerable children

in their forever homes. ACF and OCR should also survey their programs to consider whether additional waivers of HHS grant conditions—waivers the Biden Administration revoked in 2021—are needed for faith-based agencies.

Additionally, Congress should pass the Child Welfare Provider Inclusion Act[62] to ensure that providers and organizations cannot be subjected to discrimination for providing adoption and foster care services based on their beliefs about marriage.

Office of Refugee Resettlement (ORR). The Office of Refugee Resettlement should be moved to the Department of Homeland Security. Having health and welfare functions managed by HHS and border security functions managed by DHS has created intolerable failures in both. HHS and ORR have forgotten their original refugee-resettlement mission and instead have provided a panoply of free programs that incentivize people to come to the U.S. illegally. Even more troubling, ORR has too often placed children into dangerous situations when releasing them into the country.

Nearly all of HHS's care, custody, and placement of children is done through cooperative agreements with private agencies, many of which may have broken federal law by inducing or being accomplices in illegal immigration. Those arrangements could be handled far more effectively by DHS. Congress should reform the Trafficking Victims Protection Reauthorization Act[63] to transfer all ORR duties for unaccompanied alien children to DHS and eliminate the *Flores* settlement agreement.[64]

Regardless of where ORR's functions reside, ORR staff and care providers should never be allowed to facilitate abortions for unaccompanied children in its custody, including by transporting minors across state lines from pro-life states to abortion-friendly states. Pregnant, unaccompanied girls in ORR custody should be treated with dignity, not trafficked across state lines to be victimized by the abortion industry. ORR should withdraw its policy of allowing elective abortions for children in ORR care and issue a new policy of instructing care providers not to allow girls to be transported for elective abortions. HHS OGC and the White House should insist that DOJ fight to defend that policy up to the U.S. Supreme Court in light of *Dobbs*.

Office of Child Support Enforcement (OCSE) Congress established Aid to Families with Dependent Children in 1935 to assist single-parent families who were suffering financially from the loss of a bread-winning husband and father. Within two decades, however, the majority of families receiving aid were dependent because of paternal abandonment rather than death. Today, nearly a third of America's children live without a father present in the home, and a fourth of them are enrolled to receive child support.

The glaring issue in child support enforcement today is a non-resident father's ability to provide full or consistent child support payments. The literature reflects this divide as fathers have been categorized as "deadbeat" dads, then as "deadbroke"

dads, and now as "disconnected" dads who do not commit to the mother and child. Child support in the United States should strengthen marriage as the norm, restore broken homes, and encourage unmarried couples to commit to marriage.

Child Support Tax Credit. National or state guidelines and tax law should be updated to ensure that nonresident parents with child support orders can receive a nondependent, child support tax credit. Single filers of up to $41,756 and married or joint filers of up to $47,646 would be eligible for a child support tax credit similar to the current earned income tax credit. Filers could receive a maximum of $538 in annual returns for one child and a maximum of $3,584 in annual returns for two or more children (based on a credit rate of 34 percent). A child support tax credit would use the low-income, nonresident parents' own earned income and history of employment to assist them further in the task of caring for their children.

The key to this policy is that it empowers fathers with their own resources and money rather than creating another government assistance program (or a fully refundable credit) devoid of the father's own monetary efforts. This way, the nonresident father's role as financial provider and relational figure is affirmed, and much-needed financial resources are given to the children.

Visitation. Visitation is key to revitalizing child support and increasing payment frequency. The most effective way to lower a nonresident parent's monthly child support order is to spend more court-accounted-for time with the child. For example, Texas combined its child support court with its visitation court to ensure that resident and nonresident parents received state-mandated financial support orders and enforceable visitation orders.

Child Support Payment and Interactive Smartphone Application. Each state should be induced to implement a high-tech, easy-to-use application to centralize child support payments. As with Venmo or Cash App, nonresident parents would link their bank accounts and provide one-click monthly payments (or contribute incrementally throughout the month while tracking how much is due). Additionally, the nonresident parents could track "informal" gifts from money, groceries, clothes, sports gear, and more through the app.

This would address one of the main issues within current child support payment systems: nonresident parents claim that they are spending much of their own money to provide for children outside of their monthly payments and resident parents' claim that they spend little and neglect their official child support orders. Currently, only the latter claim can be tracked reliably. This process would enable nonresident parents to track the amount of informal support they provide and the reason for it while ensuring that the resident parent acknowledges and accepts the contribution.

Healthy Marriage and Relationship Education (HMRE) Program. The HMRE program is part of the ACF Office of Family Assistance. The following policies should be implemented.

- **Utilize HMRE funding or grants to provide state-level high school education resources and curriculum on healthy marriages, sexual risk avoidance, and healthy relationships.** Early interventions and prevention are much more cost-effective than are efforts to reach people already in broken relationships.

- **Allow child welfare funding to be used for marriage and relationship education.** Congress should adopt the following recommendation from a report issued by members of Congress's Joint Economic Committee:

> Children are far more likely to experience abuse when they are raised outside of their married-parent family. Title II of the Child Abuse Prevention and Treatment Act provides grants to communities for the purpose of preventing child abuse and neglect, and one of the stated purposes for which the grants can be used is for efforts to increase family stability. However, Congress could change the law to make it clear that Title II funding can be used for healthy marriage and relationship education.
>
> Funding provided under Title IV-B of the Social Security Act—which provides grants to states for foster care and adoption services—can also be used for promoting healthy marriage. States should consider using some of their Title IV-B funding for providing healthy marriage and relationship education for families at risk of having their children placed in foster care.[65]

- **Provide educational information on healthy marriage and relationships at Title X family planning clinics.** HHS should require clinics it funds under Title X (family planning) to provide information to customers about the importance of marriage to family and personal well-being and refer them to available federal, state, and nonprofit marriage resources.

- **Ensure proper assessments with enough time to assess HMRE programs.** Although some widely available assessments of HMRE programs report poor outcomes, many of these assessments either utilized a poor methodology or tried to measure program success prematurely. Recent assessments have shown increasing effectiveness and positive community-level marital outcomes.[66]

  The HMRE program should receive a fair and realistic assessment. Additionally, the positive role of faith-based programs should be protected

and prioritized so that these programs do not receive undue scrutiny or pressure to conform to nonreligious definitions of marriage and family as put forward by the recently enacted Respect for Marriage Act.[67]

- **Protect from religious liberty violations faith-based grant recipients who maintain a biblically based, social science–reinforced definition of marriage and family.** Social science reports that assess the objective outcomes for children raised in homes aside from a heterosexual, intact marriage are clear: All other family forms involve higher levels of instability (the average length of same-sex marriages is half that of heterosexual marriages); financial stress or poverty; or poorer behavioral, psychological, or educational outcomes.

  For the sake of child well-being, programs should affirm that children require and deserve both the love and nurturing of a mother and the play and protection of a father. Despite recent congressional bills like the Respect for Marriage Act that redefine marriage to be the union between any two individuals, HMRE program grants should be available to faith-based recipients who affirm that marriage is between not just any two adults, but one man and one unrelated woman.

Healthy Marriage and Responsible Fatherhood (HMRF) Program. This program is located within the ACF Office of Family Assistance. Its goal, like that of the HMRE program, is to provide marriage and parenting guidance for low-income fathers. This includes fatherhood and marriage training, curriculum, and subsequent research.

- **Implement a pro-fatherhood messaging campaign.** With nearly 41 percent of children born without a married father in the home (and nearly 69 percent among black Americans), the fatherhood problem is clear. Similar to Florida Governor Ron DeSantis's 2022 fatherhood bill, HMRF funds should be used to support national messaging campaigns that affirm the role fathers play in the lives of their children, that recognize the financial hardships the fathers themselves face, and that seek to provide relationship education to fathers who were raised without a father in the home.

- **Fund effective HMRF state programs.** Grant allocations should protect and prioritize faith-based programs that incorporate local churches and mentorship programs or increase social capital through multilayered community support (including, for example, job training and social events). Programs should affirm and teach fathers based on a biological and

sociological understanding of what it means to be a father—not a gender-neutral parent—from social science, psychology, personal testimonies, etc.

ADMINISTRATION ON CHILDREN, YOUTH, AND FAMILIES (ACYF)

- **Allocate funding to strategy programs promoting father involvement or terminate parental rights quickly.** ACYF is currently considering different programs to encourage parents, especially fathers, to engage with their children in foster care. While these program ideas and initiatives are still in the early planning stages, promoting responsible parenthood to reintegrate children or at least keep a consistent male figure in the minor's life is crucial. At the same time, in cases where the father or mother does not make a sincere or serious effort to be involved in the child's upbringing, termination of parental rights for children in foster care should be swift.

OFFICE OF HEAD START (OHS)

- **Eliminate the Head Start program.** Head Start, originally established and funded to support low-income families, is fraught with scandal and abuse. With a budget of more than $11 billion, the program should function to protect and educate minors. Sadly, it has done exactly the opposite. In fact, "approximately 1 in 4 grant recipients had incidents in which children were abused, left unsupervised, or released to an unauthorized person between October 2015 and May 2020."[68] Research has demonstrated that federal Head Start centers, which provide preschool care to children from low-income families, have little or no long-term academic value for children. Given its unaddressed crisis of rampant abuse and lack of positive outcomes, this program should be eliminated along with the entire OHS. At the very least, the program's COVID-19 vaccine and mask requirements should be rescinded.

ADMINISTRATION FOR COMMUNITY LIVING (ACL)

- **Support palliative care.** Physician-assisted suicide (PAS) is legal in 10 states and the District of Columbia. Legalizing PAS is a grave mistake that endangers the weak and vulnerable, corrupts the practice of medicine and the doctor–patient relationship, compromises the family and intergenerational commitments, and betrays human dignity and equality before the law. Instead of embracing PAS, policymakers should focus on the benefits of palliative care, which works to improve a patient's quality of life by alleviating pain and other distressing symptoms of a serious illness. HHS ACL should survey their programs to ensure that they are supporting vulnerable persons of age or disability and are not facilitating or encouraging participation in PAS.

- **Readdress the National Strategy to Support Family Caregivers.** While in theory the strategy aims to support family members with duties to care for older family members, the plan is overly focused on racial and "LGBTQ+ equity." The strategy should be examined to establish an efficient plan to support caregivers and their families. There should also be a review of its COVID-19 policies.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

- **Congress should allow CMS to use the 340B data that HRSA collects rather than having CMS conduct its own survey**, especially in view of the U.S. Supreme Court's *American Hospital Association v. Becerra* decision.[69] The legislation should also create penalties for those who do not respond to HRSA's data collection.

- **Legally define the locus of service as where the provider is located during the telehealth visit rather than where the patient is.** With such a definition, states could continue to reserve their powers to establish the standards for licensure and scope of practice. The providers could ensure continuity and consistency of care no matter where their patients might move while maintaining the licenses that make the most sense for them.

  Americans are far more mobile and technologically advanced today than they were when most health care laws were written. Telehealth has become increasingly important, particularly during the height of the COVID-19 pandemic. It also has great potential in rural and other areas where there are shortages of health care providers. HRSA's Office for the Advancement of Telehealth includes a program known as the Licensure Portability Grant Program, which bolsters state efforts to reform licensing laws to maximize telehealth flexibility. HRSA does not have the authority through this office to dictate licensure laws; that power has typically been reserved to the states. However, telehealth across state lines, when permitted, is interstate commerce, which can be regulated by the federal government according to the Constitution.

- **Restore Trump religious and moral exemptions to the contraceptive mandate (also a CMS rule).** HHS should rescind, if finalized, the regulation titled "Coverage of Certain Preventive Services Under the Affordable Care Act," proposed jointly by HHS, Treasury, and Labor.[70] This rule proposes to amend Trump-era final rules regarding religious and moral exemptions and accommodations for coverage of certain preventive services under the ACA. Preventive services include contraception, and

it appears the proposed rule would change the existing regulations for religious and moral exemptions to the ACA's contraception mandate. There is no need for further rulemaking that curtails existing exemptions and accommodations.

- **Require HRSA to use rulemaking to update the women's preventive services mandate.** The contraceptive mandate issued under Obamacare has been the source of years of egregious attacks on many Americans' religious and moral beliefs. The mandate was issued as part of the women's preventive services guidelines, which were issued without any rulemaking that involved public notice and an opportunity to comment. Instead, HRSA issued and changed the mandate by simply posting changes to its website. HRSA also started off not requiring coverage of fertility awareness–based methods of family planning, then requiring them, and then removing the requirement without notifying the public. A federal judge recently ruled that this failure to undergo notice and comment in issuing the mandate is unlawful. HRSA should be required to repromulgate any women's preventive services mandates through the notice and comment process that is compliant with the Administrative Procedures Act.

  Moreover, since the Obama Administration HRSA entered into long-term contracts with the pro-abortion American College of Obstetricians and Gynecologists (ACOG) and related entities to serve as an exclusive adviser with respect to the content of this mandate, HRSA has used this arrangement to ignore comments that members of the public were sometimes able to submit in the process, and ACOG has abused its position to attack HHS's allowance of religious and moral exemptions to the contraceptive mandate. HHS should rescind these contracts and establish an advisory committee that is compliant with the Federal Advisory Committee Act and has members that are committed to women's preventive services and are not pro-abortion ideologues.

- **Expand inclusion of fertility awareness–based methods and supplies to family planning in the women's preventive services mandate.** The ACA requires coverage of and prevents insurance plans from imposing any cost-sharing requirements on women who obtain preventive care and screenings as defined by HRSA. In 2016, HHS included "instruction in fertility awareness-based methods" as part of this requirement. However, in December 2021, HHS removed that language from its list without using the notice-and-comment process or giving any rationale, both of which are mandated by the Administrative Procedures Act. In August

2022, a federal court blocked this attempt to eliminate health insurance coverage for fertility awareness–based methods of family planning from requirements that cover at least 58 million women, and the judge made his ruling permanent in December 2022. HRSA should promulgate regulations consistent with this order.

HHS should more thoroughly ensure that fertility awareness–based methods of family planning are part of women's preventive services under the ACA. FABMs often involve costs for materials and supplies, and HHS should make clear that coverage of those items is also required. FABMs are highly effective and allow women to make family planning choices in a manner that meets their needs and reflects their values.

- **Eliminate men's preventive services from the women's preventive services mandate.** In December 2021, HRSA updated its women's preventive services guidelines to include male condoms after claiming for years that it had no authority to do so because Congress explicitly limited the mandate to "women's" preventive care and screenings. HRSA should not incorporate exclusively male contraceptive methods into guidelines that specify they encompass only women's services.

- **Eliminate the week-after-pill from the contraceptive mandate as a potential abortifacient.** One of the emergency contraceptives covered under the HRSA preventive services guidelines is Ella (ulipristal acetate). Like its close cousin, the abortion pill mifepristone, Ella is a progesterone blocker and can prevent a recently fertilized embryo from implanting in a woman's uterus. HRSA should eliminate this potential abortifacient from the contraceptive mandate.

- **Withdraw Ryan White guidance allowing funds to pay for cross-sex transition support.** HRSA should withdraw all guidance encouraging Ryan White HIV/AIDS Program service providers to provide controversial "gender transition" procedures or "gender-affirming care," which cause irreversible physical and mental harm to those who receive them.

- **Ensure that training for medical professionals (doctors, nurses, etc.) and doulas is not being used for abortion training.** HHS should ensure that training programs for medical professionals—including doctors, nurses, and doulas—are in full compliance with restrictions on abortion funding and conscience-protection laws. In addition, HHS should:

1. Investigate state medical school compliance with the Coats–Snowe Amendment,[71] which prohibits discrimination against health care entities that do not provide or undergo training for abortion.

2. Ensure that the Accreditation Council for Graduate Medical Education (ACGME) complies with all relevant conscience statutes and regulations and that states have taken the affirmative steps (for example, by issuing regulations) to assure compliance with Coats–Snowe.

3. Communicate to medical schools that any abortion-related training must be on an opt-in rather than opt-out basis.

4. Require states that receive HHS funds to issue regulations or enter into arrangements with accrediting bodies to comply with the Coats–Snowe Amendment's prohibition of mandatory abortion training by individuals or institutions. The Coats–Snowe Amendment specifically requires such state regulations or arrangements.

- **Prioritize funding for home-based childcare, not universal day care.** As HRSA's Early Childhood Health page outlines, "Currently, only about half of U.S. preschoolers are on-track with their development and ready for school. And more than one in four of children (28%) who experience abuse or neglect are under 3 years old."[72] Concurrently, children who spend significant time in day care experience higher rates of anxiety, depression, and neglect as well as poor educational and developmental outcomes. Instead of providing universal day care, funding should go to parents either to offset the cost of staying home with a child or to pay for familial, in-home childcare.

- **Provide education and resources on early childhood health.** By partnering with new organizations like the Center on Child and Family Poverty, HRSA should provide resources and information on the importance of the mother–child relationship in child well-being. This should include relationship education curricula that equip mothers and caregivers to connect with and improve their understanding of their infants, toddlers, and young children.

Maternal and Child Health. Currently, the HRSA Maternal and Child Health program is collecting data on the benefits of doulas in improving the health, safety, and emotional well-being of mothers at birth. Doulas provide a patient-focused, nonmedical support system for single or married mothers that "decreases the

overall cesarean rate by 50%, the length of labor by 25%, the use of oxytocin by 40%, and requests for an epidural by 60%. Doulas often use the power of touch and massage to reduce stress and anxiety during labor."[73]

Given concerns about maternal mortality or postpartum depression that is worsened by poor birth experiences, doulas should be an active option for all women whether they are giving birth in a traditional hospital, through midwifery, or at home. Additionally, since most Doulas' services are not covered by traditional insurance programs, the Maternal and Child Health program should work to provide funding for low-income mothers.

INDIAN HEALTH SERVICE (IHS)

The Indian Health Service serves our American Indian and Alaska Native populations. Reforms are needed to improve America's ability to deliver on its promises to these important populations and must take account of cultural preferences and lifestyles, limitations due to geography (such as challenging terrain), and limited Internet access. For example, contacting individuals within some of these communities and tribes during the COVID-19 pandemic proved to be difficult because many had transient addresses and unreliable cell service.

During the transition to the Biden Administration, IHS abandoned tribes as their sources of COVID-19 tests and vaccine supplies disappeared. It is important to guard against such situations in order to preserve these tribes' access to health resources during public health emergencies (PHEs). Even before the pandemic, services available to these populations through federal resources and personnel (such as vision care) were often scarce or nonexistent.

Patients in these populations should be empowered to rely on alternatives to IHS through better access to private health care providers. Exploring positive reforms contained in the VA MISSION Act[74] could reveal similar opportunities for increased options and access for American Indians and Alaska Natives.

RURAL HEALTH

A growing concern is the decreasing access to health care services for Americans living in rural, less populated areas. Many find themselves in regions that were not previously as rural as industries move away, taking with them economic prosperity and often medical providers. Others are in essential professions such as farming that by nature necessitate living in regions with fewer city accommodations and economic opportunities. Seeking space for one's family and cultivating the land are valued goals that are deeply rooted in America's fabric.

Both Congress and an Administration must continually keep in mind how health care policies uniquely affect these regions because their market trends and populations are different from those of more populous regions. Often, rural patients face an hour's drive to the nearest medical provider or facility or have

limited or no Internet access, which restricts their access to telehealth services (especially video visits).

To improve its health care policies that affect rural regions, HHS should:

- **Reduce the regulatory burden** and unleash private innovation that can discover solutions to unique, local needs.

- **Implement or encourage policies** that increase the supply of health care providers, such as increased telehealth access and interstate licensure (a historically state matter), including for volunteers wishing to provide temporary, charitable services across state lines.

- **Encourage flexibility** in modes of health care delivery, including less expensive alternatives to hospitals and telehealth independent of expensive air ambulances.

OFFICE OF THE SECRETARY

The Secretary of Health and Human Services and the Office of the Secretary necessarily set the tone for the entire department. The Secretary is the most accountable individual within HHS and, along with his or her immediate staff, should therefore be responsible for setting the policies that govern the department's operations instead of allowing the operational divisions to assume the leading role in policymaking, thereby diffusing responsibility.

Practical reforms to enhance the Secretary's accountability should include the following:

- **Restrict HHS's ability to declare indefinite public health emergencies (PHEs).** Currently, HHS is merely required to notify Congress of such a declaration within 48 hours. Congress should establish a set time frame for any PHE, placing on the Secretary the burden of proof as to why an extension of the PHE is necessary.

- **Reinstate the HHS SUNSET (Securing Updated and Necessary Statutory Evaluations Timely) rule.**[75] Congress should codify the now-reversed Trump Administration rule that required all HHS agencies to review regulations retrospectively and publish results; without such a review, regulations expire.

- **Investigate, expose, and remediate any instances in which HHS violated people's rights by:**

1. Colluding with Big Tech to censor dissenting opinions during COVID.

2. Colluding with abortion advocates and LGBT advocates to violate conscience-protection laws and the Hyde Amendment.

The Life Agenda. The Office of the Secretary should eliminate the HHS Reproductive Healthcare Access Task Force and install a pro-life task force to ensure that all of the department's divisions seek to use their authority to promote the life and health of women and their unborn children. Additionally, HHS should return to being known as the Department of Life by explicitly rejecting the notion that abortion is health care and by restoring its mission statement under the Strategic Plan and elsewhere to include furthering the health and well-being of all Americans "from conception to natural death."

The next Administration should create a dedicated Special Representative for Domestic Women's Health. In the Trump Administration, there was a Special Representative for Global Women's Health that focused on international issues, but this position lacked authority to be the lead on international policies because of overlapping issues with the U.S. Department of State and USAID (and at times a lack of clarity as to the lead point of contact and policy decisions at the White House). The new Special Representative would serve as the lead on all matters of federal domestic policy development related to life and family with support from the DPC for implementation and coordination among agencies. In the post-*Dobbs* era, advancing support for mothers will include coordination among agencies outside of HHS, and the Special Representative would provide a clear focal point for all issues related to protecting life and serving families.

The Family Agenda. The Secretary's antidiscrimination policy statements should never conflate sex with gender identity or sexual orientation. Rather, the Secretary should proudly state that men and women are biological realities that are crucial to the advancement of life sciences and medical care and that married men and women are the ideal, natural family structure because all children have a right to be raised by the men and women who conceived them.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH (OASH) / OFFICE OF THE SURGEON GENERAL (OSG)

The Assistant Secretary for Health (ASH) is the four-star admiral for the United States Public Health Service Commissioned Corps (USPHS), and the Surgeon General (SG) is the three-star admiral.

The ASH is tasked with overseeing not only the USPHS, but also 10 regional health offices, multiple presidential and secretarial advisory committees, and other offices such as the Offices of Minority Health, Women's Health, and Population Affairs. The Secretary can further expand the ASH's responsibilities (for example, by

designating the ASH as liaison to the CDC). The SG officially oversees the daily operations of the USPHS, although those are actually under the control of the Director of the USPHS Commissioned Corps Headquarters. The SG also issues information to the public (Surgeon General's advisories, Calls to Action, and Reports), serving in effect as a key public health spokesperson for the federal government.

USPHS officers are assigned to various agencies such as the CDC, NIH, and Bureau of Prisons. Their organizational structure is similar in some respects to the National Guard's, and their salaries are paid primarily by the agencies to which they are assigned (which serves to limit USPHS appropriations). USPHS officers can be deployed on missions to respond to domestic or international crises (for example, a hurricane in Florida or an Ebola outbreak in Africa) at any time.

The USPHS should be restructured to make it more like its sister uniformed services with a more streamlined chain of command and corresponding appropriations to ensure efficiency and clarity of mission. Its core mission should be refocused to emphasize prompt, responsive deployments that meet specific criteria and are less dependent on the various agencies to which the officers are assigned. Fulfillment of specific tasks should not be duplicated by non-uniformed civil servants and USPHS officers, and any roles that can be filled by civilians should be filled by them.

The ASH and SG positions should be combined into one four-star position with the rank, responsibilities, and authority of the ASH retained but with the title of Surgeon General and some of the SG's communications responsibilities, which would include disseminating other HHS messages and sharing general medical advice without legal weight. The holder of this consolidated position, which should be filled by a health care provider, would be better positioned to ensure that the USPHS is properly focused and deployed.

With such reforms, the supporting office (previously the OASH and OSG) would be better equipped than other HHS offices or agencies to reduce silos and consolidate or eliminate duplicative functions. Congress should consider legislation that would require this office to take such actions or at least make such recommendations to the Secretary. Such legislation would require a thorough analysis of the various legal authorities impacting the department's current organizational structure.

The position previously known as the Principal Deputy Assistant Secretary for Health should be combined with and have the title of Deputy Surgeon General and become a three-star position with operational control including financial and deployment decisions. The Director of the Headquarters should be responsible for implementing the decisions of the Deputy Surgeon General.

Promoting Life and Family. In dealing with sexually transmitted diseases and unwanted pregnancies, the OASH should focus on root-cause analysis with a focus on strengthening marriage and sexual risk avoidance. Strong leadership is needed

in the Office of Science and Medicine to drive investigative review of literature for a variety of issues including the effect of abortion on prematurity and breast cancer; lack of evidence for so-called gender-affirming care; and physical and emotional damage following cross-sex treatments, especially on children. The OASH should withdraw all recommendations of and support for cross-sex medical interventions and "gender-affirming care."

Title X. The Title X family planning program should be reframed with a focus on better education around fertility awareness and holistic family planning and a Deputy Assistant Secretary for Population Affairs that understands the program and is able to work within its legislative framework (ideally, an MD). In addition, the Office of Population Affairs should eliminate religious discrimination in grant selections and guarantee the right of conscience and religious freedom of health care workers and participants in the Title X program.

In 2021, HHS reversed a Trump Administration regulation that required grantees to maintain strict physical and financial separation between Title X activity and abortion-related activity.[76] Under the Biden Administration's regulation,[77] Title X activity can be conducted alongside abortion activity without strict physical and financial separation. The regulation also requires grantees to refer for abortions despite sincere moral or religious objections. This effectively bans otherwise qualified pro-life grantees from participating in the program.

HHS should rescind the Biden Administration's regulation and reinstate the Trump Administration regulation for the program. It should also do this quickly (the Biden Administration completed its regulatory process and issued a final rule in less than nine months) and expand the potential grantee population beyond abortion providers like Planned Parenthood.

Congress should complement these efforts by passing legislation such as the Title X Abortion Provider Prohibition Act,[78] which would prohibit family planning grants from going to entities that perform abortions or provide funding to other entities that perform abortions. This would help to protect the integrity of the Title X program even under an abortion-friendly Administration.

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE (ASPR)

ASPR vs. FEMA. When the President declares a national emergency (per the Stafford Act) related to a public health emergency declared by the HHS Secretary, FEMA is activated and controls instead of HHS/ASPR. While this arrangement has some benefits because of FEMA's unique logistical capabilities, the arrangement should be reviewed—especially considering the COVID-19 pandemic—for improvements in efficiency according to expertise and available resources, reduced confusion for ASPR and among HHS agencies, and avoidance of duplicated efforts among agencies and personnel.

Strategic National Stockpile. The President should invoke the Defense Production Act,[79] which is a form of temporary takeover of private enterprises, only in the gravest circumstances. The Strategic National Stockpile (SNS) should be reformed to consider the potential supply chain disruptions of pandemics or global conflicts. Also, during the COVID pandemic, many states received ventilators from the SNS and hoarded them in places where a rush of COVID patients needing ventilators never materialized. The SNS should clarify its mission as supplier of last resort to the federal government, state governments, or first responders and key medical staff and should not portray itself as serving the public as a whole.

OFFICE OF GENERAL COUNSEL (OGC)

The Office of General Counsel is essential to ensuring that HHS is operating within the bounds of its numerous governing statutes. However, legal caution can outweigh practical necessity and often slows processes and decisions when time is of the essence. Such problems were evident both before and during the COVID-19 pandemic. Internal processes should be reformed to streamline necessary legal determinations during crises, and general processes should be reviewed for efficiency. OGC should also:

- **Rescind its PREP Act liability memo.** OGC issued a PREP Act liability memo that suspended application of civil rights and other laws in the context of the administration of covered countermeasures during the pandemic. It should be rescinded as contrary to law.

- **Rescind efforts to curtail OCR authority over conscience and religious freedom.** All OGC memos and *Federal Register* notices of organization or delegations of authority moving any OCR conscience and religious freedom enforcement to OGC, including RFRA, should be rescinded, and independent authority over these matters should be restored to OCR.

- **Encourage DOJ to repeal OLC memos allowing abortion funding despite Hyde and memos allowing federal enclave immunity to perform abortions despite the Assimilative Crimes Act.**[80]

- **Rescind legal analysis that authorized HHS to impose a moratorium on rental evictions during COVID.**

- **Rescind the OGC legal analysis saying that the injunction in *Bowen v. American Hospital Association*[81] prevents any proposed HHS regulations or enforcement actions concerning the denial of care**

to newborn infants with disabilities by covered health care entities without or against parental consent.

- **Rescind the legal analysis supporting the Biden Administration's decision to dismiss the University of Vermont Medical Center case dealing with the forced participation of a nurse in abortion in violation of law.**

- **Rescind the legal analysis restoring $200 million in Medicaid funds to California after having been found to be in violation of the Weldon Amendment by OCR.**

OFFICE OF GLOBAL AFFAIRS (OGA)

The Director of the Office of Global Affairs should have the title of Assistant Secretary so that he or she can adequately represent HHS and the Secretary and serve as the lead on global health diplomacy for the government. The designation "Director" is not understood to indicate the leadership role that this position holds in the international arena. In addition:

- **All divisions that work on international health efforts should be responsive to requests and direction from the Assistant Secretary with coordination for all health diplomacy emanating from OGA.**

- **OGA should have a clear and consistent voice for the Administration's pro-life and pro-family priorities in all international engagements.**

- **OGA should hold oversight authority for implementation of the Mexico City policy throughout all divisions.**

- **Every effort should be made to locate all OGA staff in the same building for better oversight and communication.**

- **Health attachés in various global locations should be trained in the Administration's policies with clear expectations communicated and with accountability, including replacement, when their conduct and advocacy are contrary to Administration policies and programmatic priorities.**

OFFICE FOR CIVIL RIGHTS (OCR)

Conscience Enforcement. Existing statutes that protect rights of conscience (such as the Church, Coats–Snowe, and Weldon amendments) do not explicitly

provide a private right of action that would allow victims to seek legal redress in court. At the same time, when it continues to fund governmental and private entities that violate these laws, HHS is spending taxpayer funds unlawfully. Under liberal Administrations, OCR has amassed a poor record of devoting resources to conscience and religious freedom enforcement and is often complicit in approving or looking the other way at the Administration's own attacks on religious liberty.

Congress should pass the Conscience Protection Act so that victims can pursue redress through courts without having to depend exclusively on OCR. In addition:

- **OCR should return to Trump Administration policies that initiated robust enforcement of these conscience laws.** It should restore and fully fund the Office of the Deputy Director for the Conscience and Religious Freedom Division (CRFD) and ensure that it has the necessary delegations from the Secretary to enforce these laws. The Secretary should give adequate delegations to OCR to pursue enforcement of conscience laws, including RFRA, and require all HHS components that provide funding or grants to cooperate with OCR CRFD investigations.

  The Secretary, the Deputy Secretary, and principals in other HHS divisions should endorse the remedial measures recommended by OCR CRFD and limit territorial objections and slow-down attempts by other divisional officials including OGC. HHS should withdraw funding from any violating entities that refuse to correct their behavior, and OCR CRFD should work with ASFR to ensure that all grant announcements and instruments inform grantees and applicants of their obligations to comply with federal health care conscience laws specifically as a condition of obtaining or maintaining their funding.

- **A draft OCR RFRA and religious freedom rule from the Trump Administration should be issued and finalized.** These regulations would provide a clear process for OCR's enforcement in coordination with other HHS divisions and existing HHS grants regulations.

- **HHS should reestablish waivers for state and child welfare agencies for religious exemptions, especially for faith-based adoption and foster care agencies.** It should also rescind subjective case-by-case evaluations for religious and faith-based organizations that request religious exemptions. These case-by-case determinations are currently coordinated with ACF and OCR. The recommended waivers should be granted to all states and agencies that request them, and OCR memos finding that RFRA would be violated if the waivers are not granted should be restored.

- **HHS should restore OCR authority to review requests for and render opinions on the application of RFRA to requests for religious accommodation of people, families, and doctors who cannot in good conscience take or administer vaccines, including those made or tested with aborted fetal cell lines.**

- **HHS should restore Section 1557, Section 504, and other OCR regulations and fix guidance documents.** In 2020, the Trump Administration's OCR published regulations under Section 1557 of the Affordable Care Act that restored the agency's enforcement of that law to the limits of its statutory text, deferred to the ACA's widespread use of a binary biological conception of sex discrimination, and specified that the regulation must comply with the religious exemption and abortion neutrality clauses in Title IX from which it is derived as well as the Religious Freedom Restoration Act and other laws. Courts blocked core provisions of that rule from going into effect.

  In 2022, the Biden Administration proposed to reinstate a rule contradicting the scope of the statute and imposing nondiscrimination on the basis of sexual orientation and gender identity. It is expected that this rule will be finalized in 2023 even though several courts have issued rulings against the interpretation on which it is based.

- **OCR should return its enforcement of sex discrimination to the statutory framework of Section 1557 and Title IX.** Specifically, it should:

  1. Remove all guidance issued under the Biden Administration concerning sexual orientation and gender identity under Section 1557, particularly the May 2021 announcement of enforcement[82] and March 2022 statement threatening states that protect minors from genital mutilation.[83]

  2. Issue a general statement of policy specifying that it will not enforce any prohibition on sexual orientation and gender identity discrimination in the Section 1557 regulation and that it will prioritize compliance with the First Amendment, RFRA, and federal conscience laws in any case implicating those claims. DOJ should commit to defending these actions aggressively against inevitable court challenges, including under cases such as *Heckler v. Chaney*.[84]

3. Issue a proposed rule to restore the Trump regulations under Section 1557, explicitly interpreting the law not to include sexual orientation and gender identity discrimination based on the textual approach to male and female biology taken by Congress in the ACA, the need to recognize biological distinctions as part of the sound practice of health care, and the need to ensure protections of medical judgment and conscience. DOJ should agree to defend this rule to the Supreme Court if necessary.

4. Issue a general statement of policy announcing that it plans to enforce Section 1557 discrimination bans by refocusing on serious cases of race, sex, and disability discrimination. In particular, OCR should highlight its 2019 investigation and voluntary resolution agreement with Michigan State University based on the sexual abuse of gymnasts by Larry Nassar. OCR should also coordinate with the Department of Education on a public education and civil rights enforcement campaign to ensure that female college athletes who become pregnant are no longer pressured to obtain abortions; pursue race discrimination claims against entities that adopt or impose racially discriminatory policies such as those based on critical race theory; and announce its intention to enforce disability rights laws to protect children born prematurely, children with disabilities, and children born alive after abortions.

5. Issue and finalize the Trump-era draft disability rights regulations concerning crisis standards of care and use of Quality of Life Adjusted Years (QALYs), and reissue and finalize a disability regulation (withdrawn by the Biden Administration) that prohibited discriminatory application of assisted suicide and denial of life-saving treatments for disabled newborns.

- **OCR should withdraw its pharmacy abortion mandate guidance.** OCR should withdraw its "Obligations Under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services" guidance for retail pharmacies,[85] which purports to address nondiscrimination obligations of pharmacies under federal civil rights laws and in fact orders them to stock and dispense first-trimester abortion drugs. The guidance invents this so-called requirement and fails to acknowledge that pharmacies and pharmacists have the right not to participate in abortions, including pill-induced abortions, if doing so would violate their sincere moral or religious objections. Moreover, no federal civil rights laws preempt state pro-life statutes.

- **OCR should withdraw its Health Insurance Portability and Accountability Act (HIPAA)[86] guidance on abortion.** OCR should withdraw its June 2022 guidance[87] that purports to address patient privacy concerns following the *Dobbs* decision but is actually a politicized statement in favor of abortion and against *Dobbs*. HIPAA covers patients in the womb, but this guidance treats them as nonpersons contrary to law. The guidance is unnecessary and contributes to ideologically motivated fearmongering about abortion after *Dobbs*.

AUTHOR'S NOTE: The preparation of this chapter was a collective enterprise of selfless individuals involved in the 2025 Presidential Transition Project. All contributors to this chapter are listed at the front of this volume and include former officials in the U.S. Department of Health and Human Services and other agencies, as well as academics, attorneys, and experts in the health care and insurance fields.

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