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QUARTERLY

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Why the CDF Note on the Morality of Using Some Anti-Covid-19 Vaccines Suggests a Moral Obligation to Receive SARS-CoV-2 Vaccines

Peter J. Cataldo, Ph.D.

The Congregation for the Doctrine of the Faith in its *Note on the Morality of Using Some Anti-Covid-19 Vaccines* stated that “... practical reason makes evident that vaccination is not, as a rule, a moral obligation and that, therefore, it must be voluntary” (n. 5).¹ This statement has been interpreted to mean that the CDF concludes there is no moral obligation to receive the currently available SARS-CoV-2 vaccines and that institutional and governmental “mandates” are ethically unacceptable. I will argue that there is no basis for this interpretation and that the CDF *Note* does entail a moral obligation to receive the vaccines by those for whom a vaccine is not medically contraindicated and that it does not rule out the moral legitimacy of mandates.

To interpret the CDF statement as precluding a moral obligation to receive the vaccines conflates what the CDF regards as a general rule or obligation *in principle* with moral obligation on the individual level.² Similarly,

the CDF use of “vaccination” in the statement refers to the act of vaccination in general, not to use of a specific vaccine in a specific set of circumstances. Thus, the fact that *in principle* there is no moral obligation for vaccination *per se* does not preclude a moral obligation to be vaccinated in particular situations. Similarly, the fact that it might be morally valid for individuals to refuse vaccinations in conscience generally, does not entail that there is no moral obligation for vaccination with specific pandemics, such as SARS-CoV-2, even though some individuals might refuse in conscience. Simply because individuals are free to refuse in conscience does not mean that they are not under a moral obligation to be vaccinated, or that the CDF has excluded the possibility of a moral obligation.

This important distinction between a moral obligation or lack of one *in principle* with an obligation or lack of one in particular circumstances is analogously evident in the distinction between the *in principle* moral obligation to receive food and water and the absence of this obligation as assessed in the

“Simply because individuals are free to refuse in conscience does not mean that they are not under a moral obligation to be vaccinated.”

particular circumstances of an individual patient for whom medically assisted nutrition and hydration would be ethically disproportionate.³ A moral norm considered *in principle* or in general does not necessarily apply in each and every individual case due to the particular circumstances of the case. This is a central premise, for example, in the principle of the double effect upheld in Catholic teaching and tradition where conditions are presented for assessing whether what is a moral obligation *in principle* applies in a particular case of an act that has both good and bad effects. Ultimately, the distinction is rooted in the classic distinction between something considered *per se* according to its essence and the same thing considered *per accidens* or how it is affected by its accidental features and particular circumstances.⁴

The CDF *Note* shows that while it acknowledges *in principle* that there is no moral obligation for vaccination, the moral status of vaccination in the particular circumstances of SARS-CoV-2 can be regarded as obligatory. The CDF statement about vaccination considered *in principle* should not be taken in isolation from all the other affirmations that the CDF makes about moral duties and responsibilities

related to individuals and the common good *in particular situations* such as SARS-CoV-2. This is the implication from several affirmations made by the CDF. First, the CDF reaffirms that there are differing degrees of responsibility in the case of vaccines developed using cell lines created with cells from tissue obtained from abortions and that a *prima facie* moral prohibition does not exist in the case of those who receive such vaccines. Second, the CDF points out that the grave danger posed by SARS-CoV-2 is a harm that is morally greater than any remote connection to abortion and finds that this proportionality is morally decisive. Third, the CDF also affirms that the morality of vaccination is inextricably tied to (“depends on”) the moral duty to protect one’s own health and the duty to pursue the common good. The implication is that because there is a moral obligation to protect one’s health and to pursue the common good, there is a moral obligation to use safe and effective vaccines *in this particular case* to fulfill these duties in the face of the grave danger of SARS-CoV-2, notwithstanding any lack of an obligation for vaccination *in principle*. Fourth, The CDF *Note* states that “the common good may recommend vaccination.” It is a legitimate interpretation of this statement that since there is a moral duty to contribute to the common good, and considering that in some situations vaccination is the best means to stop or prevent an epidemic, the moral permissibility of vaccination is at the same time a moral necessity for preserving the common good.

The term, “may recommend,” as it is used in connection with the common good here connotes the permissibility of legitimate authorities enacting universal measures appropriate to and determined by that good

which is held in common. Hence, “may recommend” does not have the meaning of a suggestion to individuals but refers to the moral legitimacy of institutional and governmental measures, like vaccination requirements, that are appropriate to the universal nature of the common good. Finally, the CDF states any connection to past abortions is not illicit cooperation but passive material cooperation and that “the moral duty to avoid such ... cooperation is not obligatory if there is a grave danger, such as the otherwise uncontainable spread of a serious pathological agent — in this case, the pandemic spread of the SARS-CoV-2 virus that causes Covid-19” (n. 3). The CDF

“The CDF states any connection to past abortions is not illicit cooperation but passive material cooperation.”

is again showing how moral responsibilities are not reducible to a consideration of moral obligation considered *in principle* and that such *in principle* norms must be evaluated in light of particular circumstances in order to determine an individual’s responsibilities. Given the particular circumstances of SARS-CoV-2 and given the other moral duties acknowledged by the CDF, the lack of an obligation to avoid passive material cooperation may be interpreted as being correlative with the positive obligation to be vaccinated.

Moreover, any stated or implied moral obligation to receive SARS-CoV-2 vaccines made by the Church is not about particular institutional or governmental “mandates.” Rather, any support by the Church for vaccination prescinds from the issue of how mandates may be configured and is focused instead on the status of the moral obligation for vaccination precisely as a *moral obligation*. Given this fact and given what has been explained about the relation between a moral norm *in principle* and moral obligations in individual situations, there is no leap whatsoever from what is morally permissible *in principle* to what is morally obligatory in a particular situation like SARS-CoV-2.

Claims are made that the data about SARS-CoV-2 vaccines is unsettled or that there are unanswered medical questions about the vaccines and that this purported fact is morally sufficient for avoiding the vaccines. However, the CDF asserted that these vaccines can be used in good conscience with an appropriate level of certitude.⁵ Such claims lend themselves to the false idea that Catholic moral teaching and tradition require absolute or one hundred percent certitude for human action. When it comes to the contingent and changing matters of human action, Catholic teaching and tradition have always recognized that moral or prudential certitude about the outcomes of an action is what is morally required, not absolute certitude. The Catholic tradition generally defined certitude or a certain conscience in moral matters as the lack of prudent fear of error in making a judgment that a particular act is either morally good or is immoral. The moral certitude of conscience ought to admit the possibility of error but excludes any

“When it comes to the contingent and changing matters of human action, Catholic teaching and tradition have always recognized that moral or prudential certitude about the outcomes of an action is what is morally required, not absolute certitude.”

reasonable doubt. The scientific evidence on the available vaccines for SARS-CoV-2 removes reasonable doubt about their safety and efficacy. In addition, and as attested by the CDF, there is no basis for reasonable doubt about any unethical connection to the past abortions from which cells were originally obtained to build the cell lines used in the development of the vaccines. Hence, consistent with Catholic moral teaching and tradition, a properly informed conscience on these vaccines can attain the moral certitude required for conscience to judge that taking them is morally acceptable. If this moral certitude did not exist for conscience to act on, the CDF and Pope Francis would not reach the conclusions they have about the moral acceptability of the vaccines.⁶

The moral obligation to act with a properly formed conscience is an obligation equally important as the obligation to follow one's conscience (see *Catechism of the Catholic Church*, ns. 1776–1794). Catholic teaching recognizes that the proper formation of conscience in part relies on human reason; in the context of vaccines for SARS-CoV-2, the resources of reason on which the formation of conscience depends include peer-reviewed scientific evidence presented by legitimate scientific sources and authorities. The moral obligation

to obey one's certain conscience is applicable if, and only if, one has a certain conscience that is not negligently ignorant of the facts. While Catholic teaching requires that the person follow a certain judgment of conscience, this obligation does not include a certain conscience that is based on negligent ignorance of the facts. The only erring judgement of conscience to which one is still morally bound to follow is that judgement in which one is excusably ignorant of the facts.⁷ In such cases the person is not morally culpable for any wrongdoing that might result, even though objectively the wrongdoing is still committed. There is an essential difference between a conscience based on true knowledge and one based on inexcusable ignorance of the facts.⁸ Negligent or “vincible” ignorance of the facts regarding SARS-CoV-2 abounds in today's climate, which places a special obligation on theologians and ethicists to attend to this dimension of Catholic moral teaching and tradition on conscience.⁹

The fact that the CDF did not explicitly prescribe a moral obligation to receive the SARS-CoV-2 vaccines in its *Note* does not entail that one does not exist, or that the CDF does not recognize the obligation. The only way to conclude that the CDF does not implicitly recognize a moral obligation to receive the

SARS-CoV-2 vaccines currently available is to isolate its acknowledgement of the lack of an *in principle* obligation for vaccination in general from all of the other moral affirmations it makes, and to ignore the long-standing distinction between norms considered *in principle* on the one hand and on the other their assessment in particular circumstances. A moral obligation to receive the SARS-CoV-2 vaccines is completely compatible with what the CDF states about vaccination in general and with Catholic teaching and tradition on conscience and moral certitude. ✚

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ENDNOTES

1. Congregation for the Doctrine of the Faith, *Note on the morality of using some anti-Covid-19 vaccines* (December 21, 2020), https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20201221_nota-vaccini-anticovid_en.html.
2. See, for example, The National Catholic Bioethics Center, "NCBC Statement on COVID-19 Vaccine Mandates," <https://www.ncbcenter.org/ncbc-news/vaccinemandatestatement>.
3. See United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, Sixth Edition, n. 58, https://www.usccb.org/resources/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06_0.pdf. See also Congregation for the Doctrine of the Faith, *Commentary* (August 1, 2007), n. 4, https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20070801_nota-commento_en.html.
4. See, for example, St. Thomas Aquinas, *Commentary on Aristotle's Physics*, bk. II, lect. 6, n. 3; *Summa Theologica*, I, q. 49, a. 1 c., ad 2, 3, and 4; ST I-II, q. 20, a. 5.
5. See the Note, n. 3, and see, for example, data from the Centers for Disease Control and Prevention (CDC).

6. See a video message of Pope Francis on how receiving SARS-CoV-2 vaccines is an act of love, <https://www.youtube.com/watch?v=V5dbCpmv8Mc>.
7. See Aquinas, ST I-II, q. 19, a. 5, a. 6.
8. See Jason T. Eberl, "Vaccine mandates are coming. Catholics have no moral reason to oppose them," *America The Jesuit Review* (August 10, 2021), <https://www.americamagazine.org/faith/2021/08/10/covid-vaccine-mandate-exemptions-voluntary-ignorance-241196>.
9. On the moral obligations of those producing materials on Catholic teaching about vaccine exemptions see M. Therese Lysaught, "Catholics seeking 'religious' exemptions to vaccine must follow true church teaching on conscience," *National Catholic Reporter*, September 21, 2021, <https://www.ncronline.org/news/opinion/catholics-seeking-religious-exemptions-vaccines-must-follow-true-church-teaching>.

Reflection Questions

1. How does the Church use the phrase "in principle" as it relates to moral obligations?
2. Do you agree with the article's premise that a moral obligation to receive the COVID vaccine is compatible with the CDF statement?
3. What are some other moral obligations we have as Catholic faithful that are not explicitly stated in a document?

Reflection on the Surgical Code

Becket Gremmels, Ph.D.

Steven J. Squires, Ph.D.

One hundred years ago last August as the country was on the heels of a global pandemic, the Surgical Code was finalized by Fr. Michael Bourke and enacted at Detroit-area hospitals. Just one-page long, with only 14 instructions, this “Code would come to serve as the precursor to the *Ethical and Religious Directives for Catholic Health Care Services (ERDs)*, currently in its sixth edition.

HISTORY OF THE CODE AND FR. MICHAEL BOURKE

“History repeats itself.” Believers affirm this claim; critics reject it. A mediation may bridge these sides, particularly in the Surgical Code’s case, namely that historical situations and events mimic others with slightly dissimilar contexts. The Surgical Code was written and given a *nihil obstat* and *imprimatur* in the wake of a horrific pandemic. What has been called “the Spanish flu” was first identified in military service members in the spring of 1918. It went on to infect one-third of the world’s population (500 million) and kill 675,000 in the U.S. and 50 million worldwide according to the CDC on the “1918 Pandemic.” The nation was reeling from the pandemic, prolonged conflict, and different ideas about the presence of the U.S. on the world stage. Catholic health care was present as well, serving the common good and the needs of the underserved while looking for

new ways to do so. The value of health care ethics was recognized by Catholic health care, as evidenced by an Ethical Committee at the Catholic Hospital Association (CHA) in the early 1920s.

Despite historical similarities there are stark differences, especially for Catholic health care. Religious congregations of women and men were widely involved in health care operations and administration. The provision of Catholic health care looked worlds apart from how it appears today. For instance, vowed religious practiced and taught others to care for minds, bodies, and spirits. Lay leaders were uncommon, and groups we’re accustomed to today, such as pastoral care or palliative care departments, were nonexistent or far-cries from contemporary counterparts.

“Necessity is the mother of invention.” Appreciating the Surgical Code entails equal regard for its key architect, Fr. Michael Bourke, whose bedrock was practicality as much as faith, duties to God and the faithful, and regard for the law. Fr. Bourke had a CV impressive in any and every century. He was a lawyer who served as Assistant Attorney General of Michigan, was ordained in 1914, was in the administration of St. Joseph Mercy Hospital in Ann Arbor where he was also the first hospital chaplain, and chaired CHA’s Ethical Committee, the group that crafted the Surgical Code. While at St. Joseph Mercy Hospital, he took up

communities' needs, coordinated proper care for those with cognitive and behavioral health issues, and organized and reorganized hospital departments for better service.¹

“Be practical as well as generous in your ideals. Keep your eyes on the stars, but remember to keep your feet on the ground.”² On the one hand, the Surgical Code's 14 directives seem negative, like a list of don'ts. They focus mostly around Part 4 of the ERDs today and specific procedures (“before operating, the surgeon will tell the sister in charge of the OR what procedure he will perform”). As a

“Be practical as well as generous in your ideals. Keep your eyes on the stars, but remember to keep your feet on the ground.”

result, they appear heavy handed in the black-and-white compared to the 6th edition. On the other hand, this was a poster intended for surgeons that hung on OR-area walls, meant for quick reference between or during surgery. Anecdotally, we have heard it had to be anchored at the bottom due to the breeze in open-air ORs. Fr. Bourke worked on the “Code” as he worked with women and men on restructuring obstetrics and gynecology at St. Joseph Mercy Hospital to meet the needs of women and their babies. The Surgical Code is the penultimate in pragmatism for a Catholic OR — an amalgamation of moral teaching, condensed to a list of short tenets.

While it applied to just a few hospitals rather than the entire country, the Surgical Code was a precursor to the ERDs. So, we thought this an opportune time to reflect on the ERDs and their wonderful contributions to Catholic health care today.

REFLECTION ON THE ERDS OF TODAY

“I didn't have the time to make it shorter.”³ We do not appreciate often enough how much there is much to admire in the ERDs as a teaching document. They condense thousands of years of theology, hundreds of magisterial documents, and millions of pages written by theologians over the centuries into 30 pages and 77 Directives. Pause a moment to think about the precision and concision necessary for such a feat. Without these Directives, clinicians, ethicists, theologians, and leaders in Catholic health care would be forced to comb through a mass of documents to find applicable teaching or relevant theological thought. Imagine trying to quickly summarize Church teaching on complying with OSHA or EEOC regulations without Directive 7, or scour *Dignitatis humanae* and other documents to explain why a Catholic hospital should hire non-Catholic chaplains without Directives 11 and 22. Both of us have worked with Catholic hospitals and Catholic bioethicists in other countries that do not have a similar document.⁴ We can personally attest to the added difficulty of working without the ERDs.

While “the Directives do not cover in detail all of the complex issues that confront Catholic health care today”, they are rather comprehensive. They provide a metaphysical foundation in “the physical, psychological, social, and spiritual dimensions of the human person.” With this basis, they delve into how

Catholic health care should attend to these social and spiritual needs (Parts 1 and 2), provide the professional-patient relationship (Part 3) as context for unique issues at the beginning (Part 4) and end (Part 5) of life, and describe the need to contribute to the common good and maintain moral integrity (Part 6).

“Definition is the formula of the essence.”⁵ Some of the content and definitions are found elsewhere in magisterial teaching (such as euthanasia or common good), and several definitions are found only in the ERDs (such as proportionate/disproportionate means and abortion). How much more difficult would complex moral dilemmas at the beginning of life be without the guidance of Directives 45 and 47? Our ability to work through end of life cases would be much poorer without the definitions in Directives 56 and 57. To be certain, the content is consistent with the broader moral tradition, but these specific definitions in these four Directives are not found anywhere else. The practicality they offer is indispensable for anyone working through dilemmas with actual patients.

“The practicality they offer is indispensable for anyone working through dilemmas with actual patients.”

While everyone finds connection with different passages or Directives, two in particular stand out to us. First, Directive 3 applies the Preferential Option for the Poor in such

practical terms that our mission in Catholic health care is indisputable. It calls us to serve, advocate for, and treat all people, but especially those who are marginalized. Yet, in the true fashion of practical, actionable guidance, it provides long enumeration of marginalized groups; only five Directives are longer in content. We have found this list to be an efficient expression of the breadth of our call to care for the poor and vulnerable.

Second, the description of the professional-patient relationship is radically different from that found elsewhere in health care today. The Introduction to Part 3 describes it as a relationship of “mutual respect, trust, honesty, and appropriate confidentiality.” Caregivers and patients both have rights and responsibilities. In health care, we frequently discuss patient rights and professional responsibilities, but too often we overlook the responsibilities of patients and the rights of professionals. Part 3 emphasizes this reciprocal give and take as it lists and describes specific rights and responsibilities for all involved. Neither the “professional nor the patient acts independently of the other; both participate in the healing process.” This mutual pursuit of a shared goal is a beacon of light in a health care system that increasingly focuses on consumer needs and trends toward the commodification of health care as a service.

“Our God-given dignity and the rights that arise from it are the ultimate foundation of all social life.”⁶ In honor of the 100th anniversary of the Surgical Code on August 1, 2021, we invite our colleagues to read the ERDs again with an eye towards appreciation for the succinctness, practicality, and direction they provide. Of the 77 Directives, 58 contain positive moral obligations, only 11 are negative obligations,

“Our God-given dignity and the rights that arise from it are the ultimate foundation of all social life.”

and 8 contain a combination of both. Contrary to some often-heard criticism, they are more than “the list of things we can’t do.” The vast majority are things we must and should do. First and foremost, “a commitment to promote and defend human dignity.” The ERDs call us to attend to the fullness of the human person to allow each person we encounter to flourish, be they patient, physician, or employee. The ERDs paint a compelling moral vision of Catholic health care done well. Health care that makes the healing presence of God known in our world and extends the healing ministry of Jesus Christ. ✚

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1. Catherine Whitaker, *A Tradition of Mercy: A History of St. Joseph Mercy and Mercywood Hospitals Ann Arbor, Michigan 1911-1979*, Catholic McAuley Health Center History, vol. 1 (Ann Arbor, MI: Catherine McAuley Health Center, 1983).
2. Theodore Roosevelt, Address at Groton School, May 24, 1904, p. 6.
3. Blaise Pascal
4. To our knowledge, only the bishops in Australia, Canada, and Ireland have created something similar for their countries.
5. Aristotle, *Metaphysics*, 1042a19
6. Pope Francis, General Audience, August 12, 2020.

Reflection Questions

1. How do you see the ERDs as helpful in your role?
2. How would you change the ERDs to meet the needs of today and the future?
3. What do you take away from this article as it relates to the history of the ERDs?

Surgical Code for Catholic Hospitals

Editor's Note: In conjunction with the feature article "Reflection on the Surgical Code" in this issue by Becket Gremmels, Ph.D., and Steven J. Squires, Ph.D., we are including the original Surgical Code from 1921 prepared by Fr. Michael Bourke for health facilities in the Archdiocese of Detroit. For additional background, please see the article "A Brief History – A Summary of the Development of the Ethical and Religious Directives for Catholic Health Services" by Rev. Kevin D. O'Rourke, OP, STM, JCD; Rev. Thomas Kopfensteiner, STD; and Ron Hamel, Ph.D., in the November – December 2001 issue of *Health Progress*. <https://www.chausa.org/publications/health-progress/article/november-december-2001/a-brief-history>

Before beginning any operation in this hospital, the surgeon is required to state definitely to the sister in charge of the operating room what operation he intends to perform.

THE FOLLOWING OPERATIONS ARE UNETHICAL AND MAY NOT THEREFORE BE PERFORMED:

One. OPERATIONS INVOLVING THE DESTRUCTION OF FOETAL LIFE. Among these are:

1. Dilatation of the **os uteri** during pregnancy and before the foetus is viable.
2. Introduction of sounds, bougies, or any other substances within the **os uteri**, during pregnancy and before the foetus is viable.
3. Induction of labor by any means whatsoever before the foetus is viable. Neither Eclampsia nor Hyperemesis Gravidarum constitute any exception to this rule.
4. Curettment of the uterus during pregnancy.
5. Craniotomy of the living child.
6. Operations for the removal of a living non-viable foetus in Extra-Uterine Pregnancy; also all operations, procedures and treatments the purpose of which is to destroy foetal life in Extra-Uterine Pregnancy.

Where the foetus attains to viability in Extra-Uterine Pregnancy, its removal is permissible.

Where a rupture occurs in Extra-Uterine Pregnancy, prompt measures should be instituted to stem the resulting hemorrhage, due caution being exercised to safeguard the life of both mother and foetus. The rent or rupture must be repaired whenever possible.

Two. ALL OPERATIONS INVOLVING THE STERILIZATION OR MUTILATION OF MEN OR WOMEN, EXCEPT WHERE SUCH FOLLOWS AS THE INDIRECT AND UNDESIRE RESULT OF NECESSARY INTERFERENCE FOR THE REMOVAL OF DISEASED STRUCTURES.

AMONG THE OPERATIONS FORBIDDEN ARE:

1. Removal of an undiseased ovary. Whenever an operation for the removal of a diseased ovary is performed, enough of such organ must be left intact if possible as will permit the same to function.
2. Removal of a Fallopian tube which is not so diseased as to require removal.
3. Section of an undiseased Fallopian tube.
4. Operations which result in obstructing the lumen of an undiseased Fallopian tube.
5. Hysterectomy where the uterus is not so badly diseased as to require the operation.
6. X-Ray Therapy, Radiotherapy, and Radiography, in the absence of their immediate indispensable need for the preservation of maternal life, are forbidden before delivery, in all cases of actual or questionable pregnancy.
7. Ventral suspensions and anterior fixations or Ventro-fixations so-called, in women of child-bearing age, in the absence of proof positive of their necessity.
8. The sterilization and castration of male patients.

The foetus may be considered viable after six calendar months.

If the foetus is known positively to be dead, operations for emptying the uterus may be performed.

The question of the presence of life, and of the necessity for the removal of the reproductive organs, or interfering therewith by surgery or medicine, must in all cases be determined by previous competent consultation.

All structures or parts of organs removed from patients must be sent in their entirety, at once, to the pathologist for his examination and report. These specimens will, after examination, be returned by him to the operator on request.

Where a pregnant mother dies before delivery an effort must be made in all cases to procure the Baptism of the unborn child.

It is possible that advances in Surgery and Medicine may render permissible some of the prohibitions of this code. Until further notification, however, the same must be followed as outlined.

The above rules are mandatory and the violation of any one of them will result in excluding the operator from the privileges of the hospital.

NIHIL OBSTAT.
Orchard Lake, 23 Julii, 1921.
MICHAEL J. GRUPA,
Cens. Libr.

MICHAEL P. BOURKE,
Chairman Ethical Committee,
Catholic Hospital Association.

IMPRIMATUR.
†MICHAEL JAMES GALLAGHER,
Bishop of Detroit — August 1, 1921.

Legal Lens

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Associate Director, supervised contributions by Jessie Bekker (J.D., M.H.A. anticipated 2023) and Darian Diepholz M.B.A., M.P.H. (J.D. anticipated 2022).

F.D.A. MOVES TO MAKE SOME HEARING AIDS AVAILABLE WITHOUT A PRESCRIPTION

Emily Anthes, *The New York Times*, October 19, 2021, <https://www.nytimes.com/2021/10/19/health/hearing-aid-fda.html>

Over 37 million American adults have a hearing impairment, but the majority do not use hearing aids. The Food and Drug Administration proposed a rule to allow hearing aids to be available without a medical exam, prescription or fitting. This rule, if passed, would allow for a new category of over-the-counter hearing aids that could improve access for millions. Costs have been attributed to one of the three reasons many with hearing loss take up to seven years before addressing the issues. Allowing for over-the-counter would decrease costs accumulated by prescriptions and audiologist visits. Currently, hearing aids can run anywhere from \$3,000-10,000 for a pair and regulations require visiting an audiologist or technician to be tested and fitted, which is not always covered by health insurance. Originally, in 2017 Congress passed the Over-the-Counter Hearing Aid Act which included

the FDA should issue draft legislation for nonprescription hearing aids by August 2020, but this did not occur due to the pandemic. In 2021, President Biden issued an executive order that the FDA must draft a rule and issue it by November 2021. The rule should encourage competition and drive prices down to make a pair available for a few hundred dollars. The rule has been published and the public can comment on the new rule for 90 days.

MEDICARE OVERPAYMENTS RULING HITS INSURERS' FRAUD DEFENSES

Stuart I. Silverman, *Bloomberg Law*, August 25, 2021, https://www.bloomberglaw.com/product/blaw/bloomberglawnews/health-law-and-business/X4INA1V4000000?bc=W1siU2VhcmNoICYgQnJvd3NlliwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWN0L2JsYXcvc2VhcmNoL3Jlc3VsdHMvZjdiYjBjZTU5ZmQ4NWRjMzA5M2MwZDY2OTNiMGY1NjliXV0-89be18e658a129b15a987fddd4c43ed0a1cad840&bn_news_filter=health-law-and-business&criteria_id=f7bb0ce59fd85dc3093c0d6693b0f562

The U.S. Court of Appeals for the District of Columbia Circuit held the Centers for Medicare and Medicaid overpayment rule was a valid use of statutory authority. CMS issued a rule that required Medicare Advantage plans to report and refund overpayment within 60 days if the insurer finds an overpayment based on an unsupported diagnosis. If an insurer failed to do so, they would be liable under the False Claims Act. UnitedHealthcare brought the suit against CMS challenging the rule. UnitedHealthcare asserted the rule should be based on “actuarial equivalence” as is used by the statute for setting

the monthly per-capita rates for Medicare Advantage plans. However, the Court found this does not apply to the insurer's obligation to refund identified overpayments. Beyond overpayment refunds, the False Claims Amendments Act of 2021 would impose higher burdens of proof of defendants when rebutting the materiality of a claim to prove a lack of materiality with "clear and convincing evidence."

FEDERAL AUDITS OF TELEHEALTH TO SHAPE ITS POST-PANDEMIC FUTURE

Christopher Brown, *Bloomberg Law*, September 8, 2021, https://www.bloomberglaw.com/product/blaw/bloomberglawnews/health-law-and-business/X1L60B10000000?bc=W1siU2VhcmNoICYgQnJvd3NlliwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWNOL2JsYXcvc2VhcmNoL3Jlc3VsdHMvOWU5ZDI4NGQ1ZTNINzc3NDc5YzYzZGJzJkMjQyNmEiXV0-48b4c6c52ab96b00f5888a030aece6378956d054&bna_news_filter=health-law-and-business&criteria_id=9e9d284d5e3e777479c37dbcf2d2426a

During the pandemic, providers embraced telemedicine to continue providing care to patients who would have lost access due to COVID-19 restrictions and federal regulators had removed barriers to telehealth for Medicare and Medicaid. By April 2020, telehealth use accounted for almost one-third of outpatient encounters. Now, telehealth use has stabilized at 13-17% of encounters. Prior to the pandemic, Medicare limited telehealth coverage to rural areas, but temporary waivers on these limits to reimbursement allowed for the increase in telehealth usage during the pandemic. Most of these changes will expire with the public health emergency, so policy makers are starting to think about permanent coverage. However, recently the Justice Department and the Office

of Inspector General of the Department of Health and Human Services announced a \$4.5 billion health-care "takedown" of telemedicine companies. This audit is the first chance to truly analyze the integrity risks and appropriate safeguards for telehealth. The OIG plans to release the reports and policy recommendations later this year. The final goal is for CMS to use OIG recommendations to create appropriate guardrails for telehealth post-pandemic.

WORKERS WITH UNVACCINATED SPOUSES WILL PAY MORE FOR INSURANCE, A LOUISIANA HEALTH SYSTEM SAYS

Kim Bellware, *Washington Post*, October 5, 2021, <https://www.washingtonpost.com/health/2021/10/05/unvaccinated-spouse-fee/>

Beginning in 2022, Ochsner Health System, Louisiana's largest health-care system, will require a \$200 monthly surcharge if an employee's spouse or domestic partner on the company health plan is not vaccinated against COVID-19. The CEO of Ochsner claims the policy is not a "mandate" as spouses and partners can opt out for health insurance elsewhere. Currently, Oschner has 33,000 employees and is one of the first large companies in the U.S. to create a policy that includes spouses and partners. Oschner, a self-insured company, spent \$9 million on covid care for individuals who were beneficiaries of their health plan in the past year. The mandate allows for health and religious exemptions but not all employees are accepting the mandate. On September 20, over 40 filed a lawsuit to block the mandate for violating medical privacy. Similar claims have been made against other organizations, like President Biden's vaccination

rules for all federal workers. According to Joel Friedman, surcharges are legal as long as exemptions are provided and are capped to a percentage of income. Louisiana has recently begun to see its highest infection rates since the start of the pandemic, with over 1,000 new cases a day. Only 45% of the eligible population in the state is fully vaccinated.

ARIZONA AG EXPANDS LEGAL CHALLENGE TO BIDEN VACCINE MANDATES

Robert Iafolla, *Bloomberg Law News*, Oct. 22, 2021, https://www.bloomberglaw.com/bloomberglawnews/daily-labor-report/X2TVT3T4000000?bna_news_filter=daily-labor-report#jcite

Arizona Attorney General Mark Brnovich filed an amended complaint against the Biden Administration seeking to block a vaccine mandate for federal employees and contractors. The complaint alleges President Joe Biden both lacks authority to mandate vaccination and calls the mandate a constitutional violation. In his complaint, Brnovich also attacked the validity of mandating uptake of a vaccine approved under emergency-use authorization, though experts have said the argument has lost footing since the Pfizer vaccine received full FDA approval. He also made a connection in the complaint between immigration policies and the vaccine mandate, calling it discriminatory against citizens and immigrants with work visas, as undocumented immigrants would not be subject to the mandate. Brnovich called the mandate “one of the greatest infringements upon individual liberty, federalism, and the separation of powers by any administration in our country’s history” in a news release. The

recently filed amended complaint is triple the length of the first, which Brnovich filed in early September. The U.S. Justice Department declined to comment.

NO PAPERS, NO CARE: DISABLED MIGRANTS SEEK HELP THROUGH LAWSUIT, ACTIVISM

Heidi de Marco, *Kaiser Health News*, Sept. 16, 2021, <https://khn.org/news/article/no-papers-no-care-disabled-migrants-seek-help-through-lawsuit-activism/>

A federal class action lawsuit filed in the U.S. District Court for the Central District of California alleges that U.S. Immigration and Customs Enforcement and the Department of Homeland Security has discriminated against detainees by failing to supply mental and physical health care. A September feature from *Kaiser Health News* detailed the lack of medical services available for undocumented immigrants, whether detained or simply living without papers in the U.S. Currently, those with asylum status have access to private health insurance on the Affordable Care Act marketplace, or, in some cases, can get public assistance. California’s Medicaid program MediCal pays for services for people 26 and under, regardless of immigration status. Beginning next spring, it will cover income-eligible undocumented people 50 and older. Though activists are celebrating the expanded eligibility, many have faced difficulty accessing necessary care. One 60-year-old undocumented woman living in Riverside, California became blind at 46 due to a rare genetic condition. Without legal status, she could not pay for her medical care. In detention, immigrants face even harsher conditions. The class action

lawsuit calls for improved conditions rather than monetary damages. The 15 plaintiffs, most of whom were released or deported, instead seek care including provision of wheelchairs and American Sign Language interpreters. Currently, there is little to no care for disabilities for immigrants held in detention, the lawsuit alleges. Neither ICE nor Homeland Security responded to requests for comment. The trial is set for April.

NEEDLE EXCHANGES ARE TARGETED BY ECO-ROOTED LAWSUITS. A NEW CALIFORNIA LAW WILL STOP THAT.

Rachel Bluth, *Kaiser Health News*, Oct. 6, 2021, <https://khn.org/news/article/needle-exchanges-environmental-lawsuits-california-law-newsom/>

Opponents to needle exchanges are suing the programs using a new approach: under environmental regulations for causing pollution in parks and waterways. Though across California opponents have won against needle exchange programs, Gov. Gavin Newsom signed a bill in early October to put a stop to the practice. Still, the bill, drafted by physician and Assembly member Joaquin Arambula, comes after free needle exchange programs across the state had to stop or change their practices. Additionally, lawsuits challenging needle programs on other grounds can still prevail despite the state law. Meanwhile, some local ordinances have banned needle exchange programs altogether. The law will take effect on January 1, making it impossible to sue needle exchange programs under the California Environmental Quality Act, which generally applies to major construction projects. Needle exchange programs were created to curb the spread of certain communicable diseases, like HIV and hepatitis C. Opponents who have

sued under environmental laws include local officials, former law enforcement officers, and community groups. Research has, for decades, shown that needle exchange programs are not major contributors to pollution, and those who participate in those programs are more likely to properly dispose of used needles than those who don't.

MERCK WILL SHARE FORMULA FOR ITS COVID PILL WITH POOR COUNTRIES

Stephanie Nolan, *The New York Times*, Oct. 27, 2021, <https://www.nytimes.com/2021/10/27/health/covid-pill-access-molnupiravir.html>

Merck has promised a royalty-free license for its Covid-19 pill that would allow poorer nations to manufacture the pill and sell it inexpensively. The news comes amid a vaccine shortage in many low-income countries. The agreement with nonprofit Medicines Patent Pool will provide sublicensing for the antiviral pill's formulation to 105 countries. The pill, called molnupiravir, will be manufactured mostly in Asian and African countries. Merck's own data shows the pill reduced hospitalizations and deaths due to Covid by fifty percent. It is awaiting regulatory approval. Treatment will cost \$20 for five days for the generic drug. Advocates supported Merck's unusual decision. It came after the company granted licenses to eight Indian drug makers, who they worried would not be able to make enough of it to support access in all low-income countries that could potentially benefit from it. Merck will assist in the technology transfer. Medicines Patent Pool director Charles Gore called the agreement "the first transparent public health license for a Covid medicine." Merck's licensing agreement specifically prohibits sales in middle income countries, like China and Russia. Merck

will instead continue to sell the drug at much higher prices in middle income countries. The agreement also excludes most countries in Latin America.

RELIGIOUS HEALTHCARE PROVIDERS WIN INJUNCTION ON ACA RULES

The Associated Press, *Modern Healthcare*, Aug. 16, 2021, <https://www.modernhealthcare.com/legal/religious-healthcare-providers-win-injunction-aca-rules>

A federal district court judge in Texas permanently enjoined the Biden administration from interpreting the Affordable Care Act as requiring health care providers to provide certain treatment. Under the injunction, Judge Reed O'Connor, siding in favor of a Catholic health system and Christian medical association, ruled that the law could not be read to require religious providers to perform abortions or gender-transition treatment. The U.S. Department of Health and Human Services argued it does not currently require provision of

such procedures. O'Connor found basis for the injunction in an earlier ruling that found HHS had violated the Religious Freedom Restoration Act. A federal judge in North Dakota issued a similar decision last January, which the Biden administration is now appealing. The Texas lawsuit dates back to 2016, when the Obama administration's HHS issued the ACA-related rules. At the time, HHS interpreted its rules to show that, for example, health care institutions which provided hysterectomies would need to do so for transgender men. In 2019, O'Connor voided the rule language which barred discrimination based on gender identity or pregnancy termination. The Supreme Court ruled in 2020 that sex discrimination included discrimination based on gender identity, and in May, HHS said its rule interpretations would follow the Supreme Court's ruling while abiding by previous lower court rulings. O'Connor found HHS's position to be contradictory. ☩

Literature Review

Reviewed by Jacquelyn Harootunian-Cutts,
Ph.D. Student

Darbyshire, Philip, Leanne Patrick, Shaun Williams, Nichole McIntosh, and Robin Ion. “The Culture Wars, Nursing, and Academic Freedom.” *Journal of Advanced Nursing* 76, no. 11: 2786–89. Accessed October 19, 2021. doi:10.1111/jan.14507.

In a searing critique of the contemporary Culture Wars, Darbyshire et al. pose a charter for nursing education that resists the forces restricting academic freedom. The authors are concerned that the excesses of the current climate of fear restrict good nursing education from multiple political angles. Faced with potential professional consequences of engaging contentious topics or challenging the opinions of students, faculty have the choice to weather efforts to have them “cancelled” or shy away from debate. Since nurses would do a disservice to their trainees and patients by ignoring many of the topics at the heart of good care, the authors believe that it is time to restate the importance of academic freedom. The authors seem to presume a definition of academic freedom that is both negative — the freedom from interference in their confrontation of polemic — and positive — the freedom to form their students in critical thinking by challenging beliefs and offering alternative critiques.

The call for challenging the beliefs of students, modeling critical thinking, and engaging controversial issues in health care is robust.

Darbyshire et al. note that nurses engage people on many levels in the provision of care and stress the need of nurses to learn how to respond with empathy and, if needed, respectful disagreement. These are especially important skills at a time when misinformation and extreme positions regarding COVID-19, public health interventions such as masks, and vaccines are the loudest voices in some areas of American life.

Ironically, even though the authors call for “nuanced discussion and collegiate debate” (p.2786), they take a totalizing view of those who would challenge the status quo of hegemony in academic discourse. While the features of “cancel culture” that Darbyshire et al. have identified are a worrisome feature of the current Culture Wars, they seem to miss the more balanced critiques that arise even in this polarized climate on the same topics.

Reichberg, Gregory M. “Scholastic Arguments for and against Religious Freedom.” *Thomist: A Speculative Quarterly Review* 84, no. 1 (January 1, 2020): 1 – 50.

Reaching back to the Scholastic period of Catholic thought, Reichberg explores three views of religious freedom: those of St. Thomas Aquinas, Francisco de Vitoria, and Francisco Suarez.

For Aquinas, true faith must be voluntary. Therefore, one cannot compel nonbelievers into the Christian faith; compulsion cannot create the necessary movement in the will. Aquinas

does hold that the medieval church does have power to compel apostates and heretics back into orthodoxy. Reichberg clarifies this position by showing how Aquinas links this power of enforcement back to baptismal vows. Additionally, Christians are, in Aquinas's view, free to defend their faith and faith expression from attack. However, Aquinas does not permit Christians to wage war to force others to become Christian.

Vitoria takes a stronger and more nuanced stance opposing compulsion and coercion in matters of faith. Vitoria is highly suspicious that even indirect coercion within Christian countries will be effective, even if it can be justified. Vitoria also notes that outside the borders of Christendom, Christians can only oppose sinful religious practices with force when it violates natural law and harms others. Within Christendom, Vitoria operates under the assumptions of the day that temporal power and spiritual power are closely tied, forming an ecclesial body together, and that measures to preserve Christianity are also measures to preserve temporal order.

Lastly, Reichberg dissects the arguments offered by Suarez. Suarez also holds that force outside of Christendom is unjustified unless there are sinful practices which harm others, such as human sacrifice, or prevent Christians from living their faith. Similarly, Suarez allows for the outlaw of public pagan practices within Christendom, though only by official temporal power. Here he differs from Vitoria in offering minimal protection for the religious practice of the other Abrahamic faiths. Suarez also allows for a form of Christian exceptionalism wherein Christian temporal powers may use force to protect the practice of Christianity beyond its

borders, but other temporal powers may not do the same on behalf of other faiths.

While Reichberg does not take a strong normative view of how these trends relate to the view of religious freedom taken by Vatican II and *Dignitas Humanae*, the investigation of Scholastic views is useful for considering a Catholic response to new trends in American political life regarding religious freedom.

McGovern, Thomas W., Anthony T. Flood, and Paul J. Carson. "COVID-19 Policy-Making in a Country Divided: Catholic Social Teaching as a Path to Unity." *The Linacre Quarterly* 87, no. 4 (November 2020): 407 — 24.

McGovern, Flood, and Carson offer an analysis of the various approaches to nonpharmaceutical interventions (NPI) used to curb the spread of COVID-19. In this piece, the authors chart a middle way between utilitarian indefinite suspension of civil liberties and libertarian extreme individual freedom by way of Catholic Social Teaching (CST). These positions have frequently been situated in the multi-layered American COVID-19 responses as competing goods. This article responds to both the goods sought by each position as well as the faults of each position. NPIs are not without their risks, so balancing the risks and benefits of NPIs with the risks and benefits of normal human interaction during a pandemic is key.

The morbidity and mortality associated with COVID-19 should be something that people are free from. Equally, people should be free to participate in religious, social, and economic activities that help contribute to human flourishing. CST provides a valuable

lens because it unites the dignity of the human person with a specific conception of the common good. In the Catholic tradition, the common good is *not* merely the sum total of all individual good, so a rejection of libertarian freedom is key. A Catholic conception of the common good encompasses both the individual good rooted in individual dignity, but also collective or shared goods that cannot be achieved without others. This framework implies that we cannot be shut down forever and that we each have responsibilities to the common good rooted in dignity. As we continue to face changing circumstances, such as debate over vaccine mandates, this framing of CST can keep the debate in terms that respect the dignity of the human person and the common good.

SYNTHESIS

The COVID-19 pandemic has in some ways inflamed the polarization of the United States. From the curtailment of academic freedom via the Culture Wars, to the difficulties of respecting and protecting freedoms during pandemic — especially religious freedoms — debate has been fierce at every turn. This collection of articles demonstrates the resources that are available to try to imagine what people are attempting to articulate when invoking concerns about freedom. At first blush, contemporary concerns regarding religious freedom may not resemble what the Scholastics

had in mind, but we can model our responses on their arguments. The Scholastics provide a framework for allowing temporal power to step in when practices harm other people and for restraining force for compelling unbelievers to belief. We can use these ideas now to animate our efforts to help as many people to become vaccinated as possible, or keep the community safe if there are practices that contribute to serious harm to others. Similarly, our current NPIs and vaccine efforts need to reflect the middle way of CST and respect deeply the dignity of each human person while also asking each person to take responsibility for contributing to the common good; this balanced approach can help all people exercise their freedom more fully. Finally, we can learn from the excesses of pandemic debate and try to encourage more constructive manners of engaging with those who disagree with us while understanding that power dynamics sometimes require confrontation and a prophetic calling out of sin. Despite this, we should remain humble in our efforts and join with educators to encourage those currently training to enter the field of health care to learn and practice critical thinking. ✚

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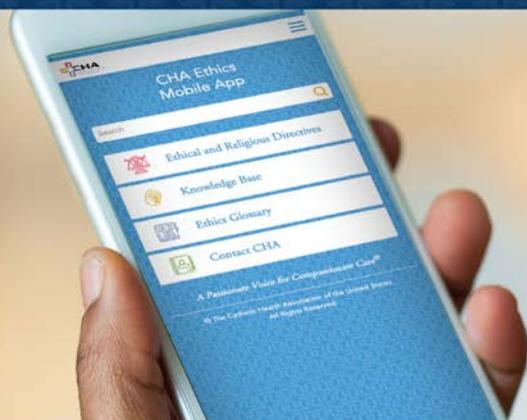


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