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Preface

This edition features an article by Kathi Aultman, M.D., et al., which first analyzes the Adverse Events (AEs) reported to the Food and Drug Administration (FDA) after use of mifepristone as an abortifacient; and second, analyzes maternal intent after ongoing pregnancy and investigates hemorrhage after mifepristone alone. The authors conclude: (1) that significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient; (2) a pre-abortion ultrasound should be required to rule out ectopic pregnancy and confirm gestational age; (3) the FDA AER system is inadequate and significantly underestimates the adverse events from mifepristone; (4) a mandatory registry of ongoing pregnancies is essential considering the number of ongoing pregnancies especially considering the known teratogenicity of misoprostol; and (5) the decision to prevent the FDA from enforcing REMS during the COVID-19 pandemic needs to be reversed and REMS must be strengthened.

The second article, by psychologists Christopher H. Rosik, Ph.D., G. Tyler Lefevor, Ph.D., and A. Lee Beckstead, Ph.D., discusses persons with minority sexual orientations that do not identify as lesbian, gay, or bisexual (LGB). They examine a sample of sexual minorities with diverse religious and sexual identity labels to determine if those rejecting versus adopting an LGB identity were different in terms of religious, sexual, relational, and health characteristics. Results suggest those who reject an LGB identity are more likely to be religiously active, full members of their church, and highly intrinsic and theologically conservative in their religious viewpoint. They further report having slightly more lifetime heterosexual attractions, fantasies, and behaviors; greater internalized homo-negativity; and being more interested in having children and a child-centered family life. They were also more likely to be single and celibate or in a heterosexual relationship. Contrary to expectations, these differences were not associated with health differences in depression, anxiety, and social flourishing. LGB identified participants did report higher life satisfaction than those rejecting an LGB identity, but this difference was not interpretively meaningful when considered in reference to population norms. The authors conclude with a discussion of the potential implications of their findings for research, legal and professional advocacy, and clinical care.

Professor Robert Joseph Casey, M.D., Ph.D., in the third article, examines value-based costing of anti-cancer drugs in an individual and societal framework. Americans have benefitted from a declining cancer incidence and improving prognosis over the past two decades, during which time rising prices for anti-cancer drugs have proportionally outstripped rising expenditures for overall cancer care and total national health expenditures. To meet the economic challenges, remedies

have been proposed to base compensation on relative survival measurements perhaps taking into account associated drug toxicities, disabilities, and disease progression. While there are advantages for knowing the economic costs determined from so-called "value-based" methodologies, it must be recognized that the measured values are impersonal, incomplete, and always biased. This article advocates grounding decisions regarding cancer care and pharmaceutical costs on the ethical principles of human dignity and the common good.

In the fourth article, constitutional attorney Paul Benjamin Linton provides the first comprehensive list of pre-***Roe v. Wade*** abortion (and abortion-related) convictions that were affirmed on appeal, beginning with cases decided in the 1840s, and ending with a handful of convictions affirmed after ***Roe*** was decided in which the defendants were not licensed physicians. He notes that even after the effort to "liberalize" abortion statues began in 1967, culminating in thirteen States adopting one version or another of the Model Penal Code provision on abortion, and four other States enacting abortion-on-demand statutes, there were more than 60 convictions of both medical professionals and lay persons for performing abortions between 1967 and the early 1970s. The research set forth in this article contributes to the ongoing debate over the history of abortion, enforcement of abortion laws, and abortion regulation in the United States.

The ***Verbatim*** section is a position statement by the American College of Pediatricians. It presents the laboratory and clinical evidence demonstrating that exposure to noxious stimuli negatively affects the human fetus as early as 12 weeks gestation (and possibly earlier). Because of the resulting acute stress responses and subsequent potential long-term negative effects, ACPeds concludes that avoiding, mitigating, and directly treating fetal, neonatal, and pediatric pain is a medical and ethical obligation.

Barry A. Bostrom, J.D.
Editor-In-Chief

Articles

Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019

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Donna J. Harrison M.D.,[**] Benjamin D. Beran M.D.,[***]
Michael D. Lockwood D.O.,[****] Sigmund Seiler M.D.[*****]

ABSTRACT: *Objectives*: Primary: Analyze the Adverse Events (AEs) reported to the Food and Drug Administration (FDA) after use of mifepristone as an abortifacient. Secondary: Analyze maternal intent after ongoing pregnancy and investigate hemorrhage after mifepristone alone.

Methods: Adverse Event Reports (AERs) for mifepristone used as an abortifacient, submitted to the FDA from September 2000 to February 2019, were analyzed using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAEv3).

Results: The FDA provided 6158 pages of AERs. Duplicates, non-US, or AERs previously published (Gary, 2006) were excluded. Of the remaining, there were 3197 unique, US-only AERs of which there were 537 (16.80%) with insufficient information to determine clinical sever-

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ity, leaving 2660 (83.20%) Codable US AERs. (Figure 1). Of these, 20 were Deaths, 529 were Life-threatening, 1957 were Severe, 151 were Moderate, and 3 were Mild.

The deaths included: 9 (45.00%) sepsis, 4 (20.00%) drug toxicity/overdose, 1 (5.00%) ruptured ectopic pregnancy, 1 (5.00%) hemorrhage, 3 (15.00%) possible homicides, 1 (5.00%) suicide, 1 (5.00%) unknown. (Table 1)

Retained products of conception and hemorrhage caused most morbidity. There were 75 ectopic pregnancies, including 26 ruptured ectopics (includes one death).

There were 2243 surgeries including 2146 (95.68%) D&Cs of which only 853 (39.75%) were performed by abortion providers.

Of 452 patients with ongoing pregnancies, 102 (22.57%) chose to keep their baby, 148 (32.74%) had terminations, 1 (0.22%) miscarried, and 201 (44.47%) had unknown outcomes.

Hemorrhage occurred more often in those who took mifepristone and misoprostol (51.44%) than in those who took mifepristone alone (22.41%).

Conclusions: Significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient. A pre-abortion ultrasound should be required to rule out ectopic pregnancy and confirm gestational age. The FDA AER system is inadequate and significantly underestimates the adverse events from mifepristone.

A mandatory registry of ongoing pregnancies is essential considering the number of ongoing pregnancies especially considering the known teratogenicity of misoprostol.

The decision to prevent the FDA from enforcing REMS during the COVID-19 pandemic needs to be reversed and REMS must be strengthened.

Conflict of Interest Statement: The authors did not report any potential conflicts of interest. Authors note that although Dr. Harrison is an associate editor for Issues in Law and Medicine, she recused herself from any involvement in the peer review process for this manuscript.

Keywords: Mifepristone, Mifeprex, RU-486, Misoprostol, Abortifacient, Medical Abortion, Abortion Pill, Medical Abortion Complications, No touch abortion, DIY Abortion, Self-Administered Abortion, Adverse Events, Adverse Event Reports, Post-marketing Surveillance, FAERS, Drug Safety, Emergency Medicine, FDA, REMS, Risk Evaluation Mitigation Strategy.

Introduction

The application for mifepristone (RU-486, RU-38486, Mifeprex) as an abortifacient was submitted to the Food and Drug Administration (FDA) in 1996 by the Population Council, which was given the manufacturing and distribution rights from Roussel Uclaf.[1] The Population Council partnered with Danco Laboratories, newly created in 1995, and gave them the manufacturing, marketing, and distribution rights. The FDA approved mifepristone in September 2000 under restricted distribution regulations (Subpart H) due to the FDA's conclusion that restrictions "on the distribution and use of mifepristone are needed to ensure safe use of this product."[2]

Included in these restrictions was the requirement that all serious Adverse Events (AEs), after the use of mifepristone as an abortifacient, be reported to the FDA by Danco as part of post-marketing surveillance. According to the FDA,[3] the purpose of such post-marketing surveillance includes identification of potential risks recognized after the time of approval, identification of unexpected deaths, causal attribution of AEs based on the product's known pharmacological action, and AEs for which a Risk Evaluation Mitigation Strategy (REMS) is intended to mitigate the risk.

In 2006, in response to the deaths of 4 women from a rare bacterial sepsis from *Clostridium sordellii (C. sordellii)*, the FDA and CDC convened a workshop, during which mifepristone alteration of the immune system was detailed, and they concluded that such alteration could lead to impaired ability to respond to *C. sordellii* toxin.[4] There is

[1] Citizen petition re: Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Day's Gestation Final. Before the Department of Health and Human Services: Food and Drug Administration. AAPLOG. 2002. 7-10. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/Documents/2002%20Aug%2020%20Citizen%20Petition_Mifeprex.pdf

[2] Center for Drug Evaluation and Research. Approval Letter for Mifeprex NDA 20-687. February 18, 2000. Food and Drug Administration. p 5. Accessed November 16, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687approvable00.pdf

[3] US Department of Health and Human Services, Food and Drug Administration Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff. November 2019. p 7-8. Accessed Jan 16 2021. https://www.fda.gov/media/130216/download

[4] Emerging Clostridial Disease Workshop: May 11, 2006, Atlanta, GA. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health. 2006. p. 109,110. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2006%20CDC%20FDA%20Clostridial%20Disease%20Transcript.pdf

evidence that both mifepristone[5,6,7] and misoprostol[8] can suppress immune response to *C. sordellii* in animal models.

In response to the septic deaths, Planned Parenthood changed their off-label protocol from vaginal administration of misoprostol to buccal in 2006.[9,10] Yet, as we found in our analysis, sepsis deaths from *C. sordellii* and other bacteria continued to occur after 2007. All sepsis deaths occurred with either vaginal or buccal misoprostol, which were both off label routes of administration until the buccal route was authorized in 2016.[11]

In 2011, the FDA approved a Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone incorporating the original restrictions.[12] In May 2015, Mifepristone's sponsor submitted a supplemental new drug application to the FDA to obtain approval to revise the drug's labeling, which the FDA approved in 2016.[13,14] The 2016 changes in the Regimen and Prescriber Agreement extended the original gestational age limit from 49

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[5] Emerging Clostridial Disease Workshop: May 11, 2006, Atlanta, GA. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, National Institutes of Health. 2006. p. 109, 110 Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2006%20CDC%20FDA%20Clostridial%20Disease%20Transcript.pdf

[6] Webster JI, Sternberg EM. Role of the hypothalamic-pituitary-adrenal axis, glucocorticoids and glucocorticoid receptors in toxic sequelae of exposure to bacterial and viral products. J Endocrinol. 2004;181(2):212, 213, 216, 217. doi.org/10.1677/joe.0.1810207

[7] Hawes AS, Rock CS, Keogh CV, Lowry SF, Calvano SE. In vivo effects of the antiglucocorticoid RU 486 on glucocorticoid and cytokine responses to Escherichia coli endotoxin. Infect Immun. 1992;60(7):2645, 2646. doi:10.1128/IAI.60.7.2641-2647.1992

[8] Aronoff DM, Hao Y, Chung J, et al. Misoprostol impairs female reproductive tract innate immunity against Clostridium sordellii. J Immunol. 2008;180(12):8227-8229. https://doi.org/10.4049/jimmunol.180.12.8222

[9] Trussell, J, Nucatola, D, Fjerstad, M, Lichtenberg, ES. Reduction in infection-related mortality since modifications in the regimen of medical abortion. Contraception, 2014;89(3):193-196. https://doi.org/10.1016/j.contraception.2013.11.020

[10] Fjerstad M, Trussell, J, Sivin, I, Lichtenberg, ES, Rates of Serious Infection after Changes in Regimens for Medical Abortion. N Engl J Med. 2009 July 9;361(2):148-149. July 9, 2009 N Engl J Med 2009; 361:145-151. doi:10.1056/NEJMoa0809146

[11] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[12] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2011. 1-11. Reference ID: 2957855. Published June 8, 2011. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf

[13] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 1. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[14] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. 1-8. Reference ID: 3909592. Published March 29, 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s-020RemsR.pdf

days to 70 days, changed the mifepristone dose from 600 mg to 200 mg orally, changed the misoprostol dose from 400 mcg orally on Day 3 to 800 mcg buccally on Day 2 or 3, allowed non-physicians to become prescribers, reduced the number of required office visits from 3 to just one initial office visit, and allowed a repeat dose of misoprostol if complete expulsion did not occur.[15] The prescriber agreement was changed so that instead of being required to "report any hospitalization, transfusion or other serious event to Danco Laboratories,"[16] providers were only required to report deaths.[17] The requirement to report ongoing pregnancies that are not terminated was also eliminated. "The FDA approved GenBioPro, Inc.'s abbreviated new drug application (ANDA) for generic Mifeprex on April 11, 2019" and "established a single, shared system REMS for mifepristone products" without substantially changing the REMS.[18]

During the COVID-19 pandemic the Maryland District Court issued a preliminary injunction prohibiting the FDA from enforcing the in-person dispensing and signature requirements contained in the mifepristone REMS.[19] This decision eliminated the need for an initial office visit for dispensing the medication and opened the door for dispensing of the drug via telehealth with no actual clinician contact. On January 12, 2021, the Supreme Court enabled the FDA to enforce the mifepristone REMS.[20] These requirements are essential for the safety of women and must be kept in place.

The first systematic analysis of these Adverse Event Reports (AERs) obtained by the Freedom of Information Act (FOIA), was published by Gary and Harrison in 2006.[21] This paper extends that analysis to AERs not previously published and augments the scant published literature on mifepristone safety.

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[15] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p.7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[16] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2011. p. 7. Reference ID: 2957855. Published June 8, 2011. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf

[17] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. p. 6. Reference ID: 3909592. Published March 29, 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s-020RemsR.pdf

[18] Questions and Answers on Mifeprex. Food and Drug Administration. March 28, 2018. Updated 4-12-2019. Accessed November 13, 2020. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex

[19] American College of Obstetricians and Gynecologists, et al., v. Food and Drug Administration, et al., No. 20-1320, 2020 WL 3960625 (D. Md. July 13, 2020). Accessed November 16th, 2020. https://www.courthousenews.com/wp-content/uploads/2020/07/093111166803.pdf

[20] FDA v ACOG. SCOTUS. 20a34_3f14. Accessed January 20, 2021. https://www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf

[21] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

Objectives

Primary: To analyze and codify the significant adverse events and their treatment after the use of mifepristone as an abortifacient, extending the previously published analysis by Gary in 2006.[22] Secondary: To examine maternal decisions in the case of ongoing pregnancy after attempted mifepristone termination, and to determine if failing to take misoprostol after mifepristone increased the risk of hemorrhage.

Materials and Methods

FDA AERs related to the use of mifepristone from September 2000 to February 2019 were obtained through the Freedom of Information Act (FOIA) from the FDA, and a comparison was made with FDA reports available online on the FDA Adverse Events Reporting System (FAERS) Dashboard.[23] Duplicate AERs were identified by comparing FDA case identification numbers, manufacturer identification numbers, dates of treatment, patient age, and descriptions of case scenarios to ensure that each case was included only once in this analysis. The authors excluded duplicates, cases originating outside of the United States, and cases previously published in the Gary analysis[24] (Figure 1).

One of the concerns in looking at AEs is the risk of falsely assigning causality. The FDA does not give guidance for determining causality for AEs in the AERs but does give guidance for selecting AEs for inclusion in the Adverse Reaction section of the Drug Label.[25] They recommend that, "Decisions on whether there is some basis to believe there is a causal relationship are a matter of judgment and are based on factors such as" the "frequency of reporting," "the extent to which the adverse event is consistent with the pharmacology of the drug," "the timing of the event relative to the time of drug exposure," and other factors. Although a causal relationship cannot be attributed with certainty to all reported AEs for a drug, a causal relationship seems probable for each of the categories of AEs we chose to analyze based on these factors, except for ectopic pregnancies and some of the deaths. Ectopic pregnancies were included in our analysis

[22] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[23] FDA Adverse Events Reporting System (FAERS) Public Dashboard. Food and Drug Administration. Accessed November 13, 2020. https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/33a0f68e-845c-48e2-bc81-8141c6aaf772/state/analysis

[24] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[25] Guidance for Industry Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER); January 2006. P. 8. Accessed January 8, 2021. https://www.fda.gov/media/72139/download

not because there is a causal relationship, but because ectopic pregnancy is a contraindication to the use of mifepristone and the diagnosis was missed, putting women's lives at risk. The deaths must be evaluated individually to determine causality.

Because reporting is often voluntary and sporadic, there is no denominator for how many mifepristone abortions are performed in the U.S. It was therefore impossible to calculate complication rates for mifepristone and misoprostol abortions based on AER data. For clarity, we specified the denominator used in each case. Coding for severity was done using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAEv3),[26] since this was the methodology used in the original analysis of the first 607 Adverse Events.[27] The five levels of coding are: Mild, Moderate, Severe, Life-threatening, and Death.

Overall severity (Figure 1) for each unique AER was determined independently by two board-certified physicians (Obstetrics and Gynecology or Family Medicine). Since within each AER, a patient may have experienced several Adverse Events (AEs), the overall severity of the AER was based on the highest severity of its AEs. For the diagnoses we analyzed (Table 1), each AE was coded in the same manner and stratified according to type, severity, and treatment. Disagreements were resolved by discussion or review by a third board-certified Obstetrician-Gynecologist who also reviewed coding for uniformity. Surgeries, transfusions, providers, and location of treatment were analyzed and tabulated.

Ruptured ectopic pregnancies were coded as Life-threatening and unruptured ectopic pregnancies as Severe.

Infections were coded as Life-threatening when evidence of sepsis was present, or ICU-level treatment was required. They were coded as Severe if parenteral/IV antibiotics were given and Moderate if oral antibiotics were prescribed.

Life-threatening hemorrhage was defined, as in the previous analysis, to be transfusion of two or more units of packed red blood cells (PRBCs), hemoglobin less than 7, or documented large volume, rapid blood loss with clinical symptomatology of acute blood loss anemia (e.g., syncope, tachycardia, hypotension). Severe hemorrhage was defined as requiring surgical intervention and/or less than 2 U PRBCs. Moderate hemorrhage was defined as management with fluids/medication alone.

Retained Products of Conception (RPOC) was coded as Severe if a dilatation and curettage/evacuation (D&C) was performed. Ongoing viable intrauterine pregnancy was considered equivalent in severity to RPOC requiring curettage and thus Severe. When

[26] Common Terminology Criteria for Adverse Events v3.0 (CTCAE). Cancer Center Therapy Evaluation Program (CTEP); 2003. 1-77. Published December 12, 2003. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/CTCAEv3.pdf

[27] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

the ultimate outcome was unknown, the pregnancy was considered ongoing if "ongoing pregnancy" was noted or ultrasound showed cardiac motion or significant growth.

AEs which did not contain sufficient information to assign an accurate severity code were deemed "Uncodable." AERs lacking any codable information were deemed overall Uncodable.

The percent of women with significant hemorrhage after mifepristone alone was compared to those who took both mifepristone and misoprostol, to investigate the validity of the assertion that lack of subsequent misoprostol administration was a causative factor in hemorrhage after mifepristone use.[28]

Results

Adverse Event Report Overall Severity

Figure 1 summarizes the handling of the AERs provided by the FDA and their severity coding. The FDA provided 6158 pages of AERs. Of these, any duplicates, non-US, or AERs previously published in the Gary paper were excluded from the analysis. There were 3197 unique, US-only AERs of which 537 had insufficient information to determine clinical severity, leaving 2660 Codable US-only AERs. Of these, 20 were Deaths, 529 were Life-threatening, 1957 were Severe, 151 were Moderate, and 3 were Mild.

Deaths (Table 1)

Our analysis identified 23 of the 24 deaths reported by the FDA as of 2018.[29] Three of those deaths were previously published in the Gary paper[30] leaving 20 deaths (Table 1). Our analysis yielded a total of 7 sepsis deaths. These included five cases of *C. sordellii* and one case of *Clostridium perfringens*, all consistent with those reported by the FDA. There was an additional death which we categorized as a sepsis death whereas the FDA labeled this case as "delayed onset toxic shock-like syndrome" but did not include it as a sepsis death. The patient had an exploratory laparotomy revealing green pus which was culture positive for *prevotella* and *peptostreptococcus* and died intraoperatively.[31]

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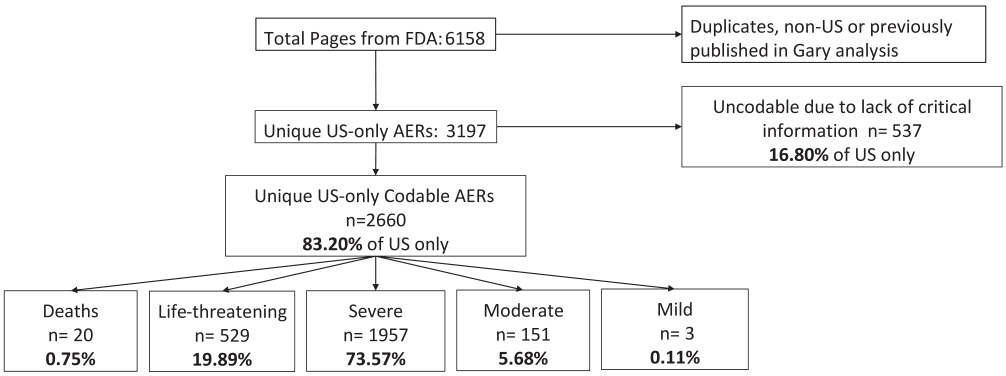
[28] Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(1):158-165. doi:10.1097/AOG.0000000000003620

[29] RCM # 2007-525 NDA 20-687 Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018. FDA. 1-2. Reference ID: 4401215. Accessed November 13, 2020. https://www.fda.gov/media/112118/download

[30] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

[31] Individual Case Safety Report number 4734082-4-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received August 4, 2005. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/Peptostreptococcus%20death%209.10277-8.pdf

Figure 1. AER Distribution



Note: From 2000 to 2016 FDA only required the manufacturer to report AE's which were severe, life-threatening or had fatal outcomes. Since 2016, FDA only requires the manufacturer to report fatal outcomes.

We categorized two deaths as suspicious for infectious death. One case was labeled by the FDA as "undetermined natural causes," however, the AER reported the cause of death as "acute visceral and pulmonary (1420 grams) congestion and edema,"[32] which is consistent with the clinical findings for sepsis/Acute Respiratory Distress Syndrome (ARDS). This patient had autopsy-proven retained products of conception and blood cultures which grew *Strep viridans* isolated at less than 24 hours incubation. One additional case which the FDA labeled "methadone overdose"[33,34] we considered suspicious for sepsis. Prior to her death, this patient had fever and chills and was treated by an outside physician with cephalexin, which would have been ineffective against infections from *C. sordellii* or anaerobic gram-negative bacilli. There was no autopsy report or toxicology report in the AER.

Non-infectious deaths include one death that the FDA listed as "natural," caused by "pulmonary emphysema."[35] This patient was a 40-year-old chronic smoker who died within hours of misoprostol ingestion and had a contusion on her head consistent

[32] Individual Case Safety Report number 9587011-03-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received May 21, 2014. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/death%20Visc%20pul%20cong.pdf

[33] Individual Case Safety Report number 4970303-0-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received April 21, 2014. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/death%2023%20yo%20meth%20overdose%20fever%20and%20chills.pdf

[34] Individual Case Safety Report number 5063156-8-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received July 27, 2006. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/methadone%20AER%20(1).pdf

[35] Individual Case Safety Report number11283049-02-00-01. Danco Laboratories, LLC. Office of Post-marketing Drug Risk Assessment, Food and Drug Administration. Received December 8, 2015. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/emphysema.pdf

with a fall, a scenario possibly related to a cardiac event or acute respiratory reaction to misoprostol. She had an intact fetus at the time of autopsy. Other non-infectious deaths included one death from a ruptured ectopic pregnancy, one from hemorrhage, 3 possible homicides, one suicide, and 4 deaths from drug toxicity/overdose. It is unknown whether the 8 women who died by homicide, suicide, or drug toxicity/overdose were screened for domestic violence, drug addiction, or depression prior to the abortion.

Infection (Table 1)

Infection was the leading cause of mortality. There were 502 cases of infection, which included 9 Deaths, 39 had Life-threatening sepses, 249 Severe infections, 132 Moderate infections, and 73 infections which were Uncodable.

Ectopic Pregnancy (Table 1)

There were 75 ectopic pregnancies. Of these, 26 were ruptured, including 1 death. Twenty-four were unruptured, and there were 25 for which the rupture status was not given. Fifty-six ectopic pregnancies were treated surgically and 11 were treated with methotrexate. The management was not documented in 7 cases. The patient who died received no treatment as she died on the way to the hospital.

Retained Products of Conception (RPOC) (Tables 1 and 2)

RPOC was the leading cause of morbidity. There were 977 confirmed cases of RPOC, including 2 molar pregnancies, and 1506 likely cases of RPOC (documentation inadequate for confirmation). Of the 2146 total D&Cs, most were for RPOC, including 897 for confirmed RPOC, 1058 for bleeding or presumed RPOC, but no pathology was provided, and 2 for molar pregnancy. A small percentage of RPOC had medical treatment or no treatment.

Hemorrhage/Bleeding (Table 1)

There were 1639 bleeding events including one death. These included 466 Life-threatening and 642 Severe events. There were also 106 events coded as Moderate, while 424 reports of bleeding were Uncodable given the information in the database.

Ongoing Pregnancy (Table 1)

There were 452 ongoing pregnancies. Of these 102 chose to keep their baby, 148 chose termination, 1 miscarried, and 201 had an unknown outcome. Of those with an unknown outcome, there were 44 patients referred or scheduled for termination, who did not follow through (39 no-showed, 3 canceled, 2 did not schedule).

Surgeries (Table 2)

There were 2243 surgeries including 2146 D&Cs, 76 laparoscopies/laparotomies without hysterectomy, 7 hysterectomies, and 14 other surgeries. Of the hysterectomies, 3 were performed for sepsis, 2 for hemorrhage, 1 for a cervical ectopic, and 1 for placenta accreta. There were 1291 surgeries performed in the hospital or ER and 952 in an outpatient setting. Of the 2146 D&Cs, 1194 were performed in the hospital or ER, and 952 in an outpatient setting. Of the 2146 D&Cs, 1194 were provided by the Hospital or ER, 853 by the abortion provider, and 99 by another outpatient provider.

Transfusions (Table 2)

Four hundred and eighty-one patients required blood transfusion following medical abortions. Of these, 365 received 1 to 10 units packed red blood cells (PRBCs) alone, 1 received fresh frozen plasma (FFP) alone, 8 received a combination of PRBCs and FFP, and 107 received an unknown amount of blood product.

Relationship of Misoprostol Use to Hemorrhage (Table 3)

The use of mifepristone with misoprostol was associated with a higher incidence of hemorrhage than the use of mifepristone alone. Of the 3056 women who took both mifepristone and misoprostol, 1572 (51.44%) hemorrhaged, whereas, among the 58 women who did not take misoprostol, only 13 (22.41%) hemorrhaged. It was unclear whether 84 patients took misoprostol or not. Fifty-four (64.29%) of them hemorrhaged. The hemorrhage rate was higher for the mifepristone with misoprostol group as compared to the mifepristone alone group even if all the unknowns were assigned to the mifepristone alone group or vice versa.

Table 1. Diagnoses[a]

Deaths	Deaths (n)	Deaths (%)	Deaths: % of (3197) Unique US AERs (%)	Organism (%)
Sepsis	9	45.00%	0.28%	
Sepsis confirmed	*7*	*35.00%*	*0.22%*	*100%*
Clostridium sordellii	*5*	*25.00%*	*0.16%*	*71.43%*
Clostridium perfringens/ Peptostreptococcus	*1*	*5.00%*	*0.03%*	*14.29%*
Peptostreptococcus	*1*	*5.00%*	*0.03%*	*14.29%*
Sepsis Likely, Unknown Organism	2	10.00%	0.06%	
Visceral and Pulmonary Congestion consistent with ARDS/sepsis	1	5.00%	0.03%	
Fever/chills treated with cephalexin, found dead[b]	1	5.00%	0.03%	
Ruptured Ectopic Pregnancy	1	5.00%	0.03%	
Hemorrhage	1	5.00%	0.03%	
Possible Homicide	3	15.00%	0.09%	
Suicide	1	5.00%	0.03%	
Drug Toxicity/Overdose	4	20.00%	0.13%	
Unknown[c]	1	5.00%	0.03%	
Total Deaths	**20**	**100%**	**0.63%**	
Infections, Level of Severity	**Infections (n)**	**Infections (%)**	**Infections: % of (3197) Unique US AERs (%)**	
Death	9	1.79%	0.28%	
Life threatening infection/sepsis	39	7.77%	1.22%	
Severe infection (IV anitbiotics)	249	49.60%	7.79%	
Moderate infection (oral antibiotics)	132	26.29%	4.13%	
Uncodable[d]	73	14.54%	2.28%	
Total Infections	**502**	**100%**	**15.70%**	

Ectopic Pregnancies, Rupture Status	**Ectopic Pregnancies (n)**	**Ectopic Pregnancies (%)**	**Ectopic Pregnancies: % of (3197) Unique US AERs (%)**	
Ruptured[e]	26	34.67%	0.81%	
Unruptured[f]	24	32.00%	0.75%	
Surgical Treatment	13	17.33%	0.41%	
Methotrexate Treatment	11	14.67%	0.34%	
Unknown Rupture Status[g]	25	33.33%	0.78%	
Surgical Treatment	18	24.00%	0.56%	
Unknown Treatment	7	9.33%	0.22%	
Total Ectopic Pregnancies	**75**	**100%**	**2.35%**	
Ectopic Pregnancies, Level of Severity	**Ectopic Pregnancies (n)**	**Ectopic Pregnancies (%)**	**Ectopic Pregnancies: % of (3197) Unique US AERs (%)**	
Death	1	1.33%	0.03%	
Life Threatening (Ruptured, survived)	25	33.33%	0.78%	
Severe (Not Ruptured)	24	32.00%	0.75%	
Uncodable	25	33.33%	0.78%	
Total Ectopic Pregnancies	**75**	**100%**	**2.35%**	
Retained Products of Conception (RPOC)	**RPOC (n)**	**RPOC (%)**	**RPOC: % of (3197) Unique US AERs (%)**	
RPOC confirmed	977	39.35%	30.56%	
RPOC confirmed (by pathology or ultrasound); Had D&C	891	35.88%	27.87%	
RPOC confirmed by U/S but D&C not documented	29	1.17%	0.91%	
RPOC treated medically	27	1.09%	0.84%	
Tissue at os (no D&C)[h]	27	1.09%	0.84%	
Molar Pregnancy	2	0.08%	0.06%	
No Treatment, RPOC on autopsy	1	0.04%	0.03%	
RPOC Likely	1506	60.65%	47.11%	
Had D&C, no pathology provided	1056	42.53%	33.03%	
Unknown[i]	450	18.12%	14.08%	
Total RPOCs	**2483**	**100%**	**77.67%**	

Bleeding Events, Level of Severity	Bleeding Events (n)	Bleeding Events (%)	Bleeding Events: % of (3197) Unique US AERs (%)	
Death	1	0.06%	0.03%	
Life threatening or Disabling: 2U or more transfusion or Hgb<7 or witnessed massive blood loss	466	28.43%	14.58%	
Severe: surgical intervention and/or 1 U transfusion	642	39.17%	20.08%	
Moderate: medical intervention	106	6.47%	3.32%	
Uncodable[j]	424	25.87%	13.26%	
Total Bleeding Events	**1639**	**100%**	**51.27%**	
Ongoing Pregnancies, Outcome	**Ongoing Pregnancies (n)**	**Ongoing Pregnancies**	**Ongoing Pregnancies: % of (3197) Unique US AERs (%)**	**Ongoing Pregnancies with Unknown Outcome (%)**
Desired to Keep Pregnancy	102	22.57%	3.19%	
Kept Pregnancy	101	22.35%	3.16%	
Kept Pregnancy but baby died in-utero	1	0.22%	0.03%	
Terminated Pregnancy	148	32.74%	4.63%	
Surgical Termination[k]	139	30.75%	4.35%	
Medical Termination	9	1.99%	0.28%	
Unknown Intent, miscarried[l]	1	0.22%	0.03%	
Unknown Outcome	201	44.47%	6.29%	100%
Referred D&C but did not show	39	8.63%	1.22%	19.40%
Referred D&C but cancelled	3	0.66%	0.09%	1.49%
Told to schedule/referred D&C did not go	2	0.44%	0.06%	1.00%
Unknown outcome, no other information[m]	157	34.73%	4.91%	78.11%
Total	**452**	**100%**	**14.14%**	

[a] Because of rounding, percentages may not appear to add up exactly.
[b] FDA attributed to methadone overdose.
[c] 40 year old smoker died within hours of misoprostol ingestion. Per FDA, "natural causes due to severe pulmonary emphysema."
[d] Patients with documented infection but inadequate information to determine severity.
[e] One of the ruptured ectopics died on the way to the hospital. The other 25 were treated surgically.
[f] The unruptured ectopics include two cornual ectopics, one treated surgically and one treated medically.
[g] Includes two cervical ectopics, one treated with D&C/Hysterectomy/massive transfusion and one with unknown treatment.
[h] Either with path provided, or described as RPOC, placental fragments, fetus, or tissue.
[i] Suspected RPOC indicating D&C needed, but not documented as being done.
[j] Patients with documented bleeding but inadequate information to determine severity.
[k] Includes one hysterotomy for pregnancy in non-communicating horn.
[l] After no show for surgical termination.
[m] Includes 10 with known gestational age 20-29 weeks.

Table 2. Treatment[a]

Type of Surgery	Type of surgery (n)	Type of surgery (%)	Surgery: % of (3197) Unique US AERs (%)
D&C[b]	**2146**	**95.68%**	**67.13%**
Hysterectomy	**7**	**0.31%**	**0.22%**
Sepsis (includes 2 deaths)	3	0.13%	0.09%
Hemorrhage after uterine perforation	2	0.09%	0.06%
Hemorrhage - Cervical Ectopic	1	0.04%	0.03%
Placenta accreta	1	0.04%	0.03%
Laparoscopy/Laparotomy without hysterectomy	**76**	**3.39%**	**2.38%**
Ectopic (Actual or Suspected)	66	2.94%	2.06%
Infection	7	0.31%	0.22%
Uterine Perforation	1	0.04%	0.03%
Salpingo oophorectomy for Torsion	1	0.04%	0.03%
Hysterotomy for pregnancy in non-communicating horn	1	0.04%	0.03%
Other Surgeries	**14**	**0.62%**	**0.44%**
Uterine Artery Embolization	1	0.04%	0.03%
Vag sutures (after 15 week surgical termination for ongoing pregnancy)	1	0.04%	0.03%
Paracenteses (multiple, same patient, death)	1	0.04%	0.03%
Necrotozing fasciitis debridement and below knee amputation	1	0.04%	0.03%
Upper and lower endoscopy for bright red bleeding	1	0.04%	0.03%
Unknown surgery for deep venous thrombosis	1	0.04%	0.03%
Angioplasty	1	0.04%	0.03%
Cholecystectomy	2	0.09%	0.06%
Appendectomy	1	0.04%	0.03%
Laceration repair (scalp, chin)	2	0.09%	0.06%
Unknown Surgery	2	0.09%	0.06%
Total	**2243**	**100%**	**70.16%**
Location of Surgery	**Location of Surgery (n)**	**Location of Surgery (%)**	
All Surgeries	**2243**	**100%**	
Hospital or ER	1291	57.56%	
Outpatient	952	42.44%	
D&C	**2146**	**100%**	
Hospital or ER	1194	55.64%	
Outpatient	952	44.36%	

Surgical Provider for D&C	Surgical Provider (n)	Surgical Provider (%)	
Hospital/ER	1194	55.64%	
Abortion Provider	853	39.75%	
Other Provider	99	4.61%	
Total	**2146**	**100%**	
Indication for D&Cs	**Indication for D&C (n)**	**Indication for D&C (%)**	
Confirmed D&C[c]	**2146**	**100%**	
RPOC (confirmed by pathology or ultrasound)	897	41.80%	
RPOC/Bleeding (no pathology provided)	1058	49.30%	
Ongoing pregnancy, surgical termination by D&C	139	6.48%	
RPOC ruled out	34	1.58%	
Ectopic evaluation	12	0.56%	
Molar pregnancy	2	0.09%	
Not able to take misoprostol	4	0.19%	
Possible D&C	**680**		
Possible RPOC, unknown treatment, possible D&C	450		
RPOC confirmed by U/S but D&C not documented	29		
Ongoing pregnancy Unknown outcome, possible D&C	201		
TOTAL (Confirmed and Possible)	**2826**		

Transfusions	Transfusions (n)	Transfusions (%)	Transfusion: % of (3197) Unique US AERs (%)
PRBC alone	**365**	**75.88%**	**11.42%**
1U	32	6.65%	1.00%
1-2U	1	0.21%	0.03%
2U	246	51.14%	7.69%
2.5	1	0.21%	0.03%
3U	45	9.36%	1.41%
4U	27	5.61%	0.84%
5U	5	1.04%	0.16%
6U	5	1.04%	0.16%
7U	2	0.42%	0.06%
10U	1	0.21%	0.03%
Other Blood products	**9**	**1.87%**	**0.28%**
1 U FFP	1	0.21%	0.03%
2 U PRBC/1 U FFP	1	0.21%	0.03%
2 U PRBC/ 4 U FFP	1	0.21%	0.03%
3 U PRBC/ 1 U FFP	1	0.21%	0.03%
4 U PRBC/ 1 U FFP	1	0.21%	0.03%
4 U PRBC/ 2 U FFP	1	0.21%	0.03%
5 U PRBC/ 4 U FFP	1	0.21%	0.03%
6 U PRBC/ 2 FFP	1	0.21%	0.03%
7 U PRBC/ FFP and Platelets unknown amount	1	0.21%	0.03%
Unknown amount (documented as given, units not recorded)	**107**	**22.25%**	**3.35%**
Total[d]	**481**	**100%**	**15.05%**

[a] Because of rounding, percentages may not appear to add up exactly.
[b] With or without suction, one with hysteroscopy.
[c] There were 8 patients who had 2 D&Cs and one who required uterine artery embolization. There were 4 perforations: two had resultant hysterectomies, one had a laparoscopy, and one received 2 U PRBCs but no documented surgery.
[d] Additionally there were 7 patients who likely received transfusion, but was not recorded, 3 patients who refused transfusion, and 1 patient for whom transfusion was considered but not given.

Table 3. Relationship of Misoprostol to Hemorrhage[a]

	Mifepristone + Misoprostol		Mifepristone alone		Unknown		Mifepristone + Misoprostol + unknown[b]		Mifepristone alone + unknown[c]	
	n	%	n	%	n	%	n	%	n	%
No Hemorrhage	**1484**	**48.56%**	**45**	**77.59%**	**30**	**35.71%**	**1514**	**48.23%**	**75**	**52.82%**
Hemorrhage	**1572**	**51.44%**	**13**	**22.41%**	**54**	**64.29%**	**1625**	**51.77%**	**67**	**47.18%**
Death from Hemorrhage	1	0.03%	0	0.00%	0	0.00%	1	0.03%	0	0.00%
Life threatening Hemorrhage	441	14.43%	5	8.62%	20	23.81%	461	14.69%	25	17.61%
Severe Hemorrhage	633	20.71%	3	5.17%	6	7.14%	639	20.36%	9	6.34%
Moderate Hemorrhage	101	3.30%	1	1.72%	4	4.76%	105	3.35%	5	3.52%
Hemorrhage, Severity Uncodable	396	12.96%	4	6.90%	24	28.57%	420	13.38%	28	19.72%
Total US AERs	**3056**	**100%**	**58**	**100%**	**84**	**100%**	**3139**	**100%**	**142**	**100%**

[a] Because of rounding, percentages may not appear to add up exactly.
[b] Assumes all unknowns took both mifepristone and misoprostol.
[c] Assumes all unknowns took mifepristone, but not misoprostol.

Discussion

This article is critically important considering the paucity of published literature on mifepristone safety and the minimal analysis done on the AERs by the FDA.

Ectopic Pregnancies

Although reported as AEs, ectopic pregnancies are not a direct adverse event from the medication, but rather a contraindication to its administration. They were reported as adverse events because the ectopic pregnancies were missed.

The American College of Obstetricians and Gynecologists (ACOG) notes that "According to the Centers for Disease Control and Prevention, ectopic pregnancy accounts for approximately 2% of all reported pregnancies. However, the true current incidence of ectopic pregnancy is difficult to estimate because many patients are treated in an outpatient setting where events are not tracked, and national surveillance data on ectopic pregnancy have not been updated since 1992. Despite improvements in diagnosis and management, ruptured ectopic pregnancy continues to be a significant cause of pregnancy-related mortality and morbidity. In 2011–2013, ruptured ectopic pregnancy accounted for 2.7% of all pregnancy-related deaths and was the leading cause of hemorrhage-related mortality."[36]

[36] ACOG Practice Bulletin No. 193: Tubal Ectopic Pregnancy, Obstet Gynecol: March 2018; 131(3): e91-e103. doi: 10.1097/AOG.0000000000002560

Confirmed/suspected ectopic pregnancy and undiagnosed adnexal mass are contraindications to mifepristone use under current prescribing requirements. The label warnings state: "Ectopic pregnancy: exclude before treatment."[37] Unfortunately, it is difficult to rule out ectopic pregnancy by history alone because, "half of all women who receive a diagnosis of an ectopic pregnancy do not have any known risk factors."[38] According to ACOG Practice Bulletin No. 193, "The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy." Of the 75 reported ectopic pregnancies in the FDA AERs we analyzed, over a third were known to be ruptured including one death. Clearly, an ultrasound should be required prior to the administration of mifepristone to document that the pregnancy is located within the uterus. Although not 100% effective, this will screen for ectopic pregnancy, confirm gestational age, which can be inaccurate based on menstrual history alone,[39] and screen for adnexal masses, another contraindication to mifepristone use.[40]

Ongoing Pregnancies

Of the women with an ongoing pregnancy, less than a third were known to have proceeded with termination of the pregnancy, and almost a quarter were known to have kept their pregnancy; in almost half, the outcome was unknown. The significant percentage of women with ongoing pregnancy who changed their mind and chose to keep their pregnancy, after initially choosing termination, raises concerns regarding the pre-abortion counseling and informed consent they received. Women undergoing abortion should receive the same quality of informed consent and pre-procedural counseling that is standard of care prior to other medical treatment or surgery. It is imperative that women considering abortion be provided adequate and complete information and counseling on risks, advantages, disadvantages, and alternative options.

Additionally, the high percentage of women with ongoing pregnancies for whom there is no follow up or known outcome is concerning. As health care providers we are to continue to care for our patients and manage any complications, yet in the AERs we reviewed this was not typically the case for the abortion provider. Furthermore, a federal registry of known outcomes and birth defects is imperative. One of the initial FDA post-marketing requirements for Danco was a surveillance study of outcomes of ongoing pregnancies.[41] The FDA released them from this post-marketing commitment

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[37] MIFEPREX. Package insert. Danco; 2016. Approved March 2016. p. 1. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf

[38] ACOG Practice Bulletin No. 193: Tubal Ectopic Pregnancy, Obstet Gynecol: March 2018; 131(3): e91-e103. doi: 10.1097/AOG.0000000000002560

[39] Shipp, Thomas D. 2020. Overview of ultrasound examination in obstetrics and gynecology. Lit Rev current through Dec 2020. UpToDate. Edited by Barss A Vanessa. Wolters Kluwer. June 10, 2020. Accessed January 11, 2021. https://www.uptodate.com/contents/ectopic-pregnancy-clinical-manifestations-and-diagnosis/print?source=history_widget.

[40] MIFEPREX. Package insert. Danco; 2016. Approved March 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf

[41] Center for Drug Evaluation and Research. NDA 20-687. Approval Letter for MIFEPREX (mifepristone) Tablets, 200 mg to Population Council. Food and Drug Administration. Written September

in January 2008 because Danco reported that only one or two ongoing pregnancies per year were followed for final outcomes in part because of consent requirements.[42] This is disturbing in light of the percentage of women in our analysis who kept their pregnancies, as well as those with ongoing pregnancy and unknown outcomes, all of whom could have been followed for final outcomes. The significant lack of follow-up of ongoing pregnancies (44.47% with unknown outcomes) and the very minimal information on those who chose to keep the pregnancy, highlights the need for a national registry especially considering the teratogenicity of misoprostol.[43]

Relationship of Misoprostol to Hemorrhage

The Creinin study of abortion pill reversal was stopped for safety concerns due to hemorrhage in 3 of the 12 study participants.[44] One of the conclusions of that study was that "Patients who use mifepristone for a medical abortion should be advised that not using misoprostol could result in severe hemorrhage, even with progesterone treatment."[45] The authors hypothesized that the absence of misoprostol caused these women to hemorrhage. The women who had documented use of misoprostol in our database hemorrhaged at a higher rate than those documented not to have taken misoprostol.

Reporting of Adverse Events

Although not the initial goal of this study, the analysis of the AERs revealed glaring deficiencies in the AE reporting system making it difficult to properly evaluate adverse events. When mifepristone was approved in 2000, FDA required that providers "must report any hospitalization, transfusion or other serious event to Danco Laboratories."[46] This created an inherent conflict of interest as it is not in the best interest of the entities or providers to report adverse events to those regulating them. Because only severe events were reportable, this requirement likely resulted in an underestimation of moderate and mild AEs. It is also likely that some of the AEs that we coded as Mild or Moderate were actually Severe but there was not enough information in the AER for us to justify coding

28, 2000. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm

[42] 2016 03 20 FDA resp to Cit Pet.pdf. Docket No. FDA-2002-P-0364. FDA. March 29, 2016. p. 31. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2016%2003%2020%20FDA%20resp%20to%20Cit%20Pet.pdf

[43] Cytotec (misoprostol tablets). Package insert. G.D. Searle; Revised November 2012. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019268s047lbl.pdf

[44] Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(1):158-165. doi:10.1097/AOG.0000000000003620

[45] Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(1):5. doi:10.1097/AOG.0000000000003620

[46] M I F E P R E X™(Mifepristone) Tablets, 200 mg Prescriber's agreement. Food and Drug Administration. Sept 28, 2000, 1-2. Accessed November 16, 2020. http://wayback.archive-it.org/7993/20170113112742/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111364.pdf

them as Severe. In March 2016, the FDA substantially reduced the prescribing requirements and changed the drug protocol[47] and yet at the same time eliminated reporting requirements except for deaths.[48] With the later relaxation of reporting requirements, the ability to perform any relevant post-marketing evaluation of mifepristone was lost. It is imperative for the safety of women that the FDA restore and strengthen the 2011 REMS requirements.

The information in the AERs is almost exclusively obtained from abortion providers, rather than the physician treating the complication, yet in this analysis, abortion providers managed only 39.75% of surgical complications (a number which is likely much lower since these are only the cases which are known to the abortion provider). Throughout the reports, there was also a lack of detail and many patients who were simply "lost to follow up." This resulted in 16.80% of the AERs being Uncodable as to severity and likely under-coding of many AERs and AEs, as coding could only be assigned based on the scant information provided. Many of the AEs experienced by women were unknown to the abortion provider until the follow-up examination, which is troubling considering the poor follow-up rate and elimination of the requirement for an in-office follow-up visit. Some of the patient deaths were not known to the abortion provider until they saw the death in an obituary or were contacted by an outside source. Because of this, in addition to abortion providers, hospitals, emergency departments, and private practitioners should be required to report AEs.

Complications occur in the best of hands in all areas of medicine, but as physicians, we are responsible to manage those complications and follow our patients through to resolution. The findings that: 1. the most common outcome of ongoing pregnancy was unknown outcome, 2. abortion providers performed less than half the D&Cs done for complications, and 3. a third of ectopic pregnancies (missed prior to administering an abortifacient) had unknown rupture status, leave us deeply concerned regarding the care these women received. A post-marketing requirement was that there be a "cohort-based study of safety outcomes of patients having medical abortion under the care of physicians with surgical intervention skills compared to physicians who refer their patients for surgical intervention."[49] The applicant was released from this requirement because they stated that because there were so few providers without sur-

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[47] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[48] NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg: Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration. 2016. p. 3, 6. Reference ID: 3909592. Published March 29, 2016. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf

[49] Center for Drug Evaluation and Research. NDA 20-687. Approval Letter for MIFEPREX (mifepristone) Tablets, 200 mg to Population Council. Food and Drug Administration. Written September 28, 2000. Accessed November 13, 2020. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm

gical intervention skills, no meaningful study could be done.[50] Yet, that same year the FDA changed the provider agreement to allow non-physicians to become prescribers.[51] These findings highlight the importance of follow-up and management of complications by the abortion provider. Allowing any further relaxation of mifepristone prescribing requirements will put women at an even higher risk of adverse events

Limitations and Strengths

It was not possible to calculate complication rates for mifepristone and misoprostol abortions based on AER data because there is no denominator for how many mifepristone abortions are performed in the U.S. since reporting is often voluntary and sporadic. For clarity, we specified the denominators we used.

Our analysis was limited by the fact that the number of AEs for which we received reports is likely a gross underestimation of the actual number of AEs that occurred. In our analysis, the surgical management of over half the complications was performed by someone other than the abortion provider, yet treating physicians are not required to report complications. Few reports were generated by those in Emergency Departments and hospitals who treated the complications.

Our analysis was also limited by the lack of information in the AERs, including redaction of critical dates, a paucity of diagnosis and treatment information, and lack of follow up.

Our study has several strengths. Our data comes from information provided to the FDA and is the largest analysis of AERs for mifepristone abortions. This data is publicly available under the Freedom of Information Act so that anyone can verify the data for themselves. This analysis reviews all AERs not reported in the first study by Gary.[52] Although heavily redacted, there was sufficient information in over 80% of the AERs to evaluate severity. An objective standardized system, CTCAEv3, was used to code for severity, and each AER was coded by at least two board-certified obstetrician-gynecologists or family medicine physicians.

Conclusions and Relevance

This article is important because it augments the scant published literature on mifepristone safety.

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[50] 2016 03 20 FDA resp to Cit Pet.pdf. Docket No. FDA-2002-P-0364. FDA. March 29, 2016. p. 31. Accessed November 13, 2020. https://aaplog.wildapricot.org/resources/2016%2003%2020%20%20FDA%20resp%20to%20Cit%20Pet.pdf

[51] GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p. 7. Published March 2018. Accessed November 13, 2020. https://www.gao.gov/assets/700/690914.pdf

[52] Gary M, Harrison D. Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient. Ann Pharmacother. 2006 Feb 40(2):191-7. https://doi.org/10.1345/aph.1G481

Due to the lack of adequate reporting of adverse events, especially by those treating them, these unique AERs represent a fraction of the actual adverse events occurring in American women.

Significant morbidity and mortality have occurred with the use of mifepristone as an abortifacient, including at least 24 US deaths reported by the FDA from September 2000 to February 2019. Because of this and the significant morbidity associated with this drug, the FDA should consider at a minimum reinstating the original 2011 REMS and strengthening the reporting requirements. The reporting of transfusions, hospitalizations, and other serious adverse events are essential.

Given the morbidity and mortality of undiagnosed ectopic pregnancy, a clear contraindication to the use of mifepristone, an ultrasound to confirm pregnancy location is essential before mifepristone is dispensed.

Considering the significant percentage of women with ongoing pregnancies who chose to continue their pregnancy, there must be reasonable waiting periods, parental involvement, and adequate pre-abortion counseling on all pregnancy options. It is also critical that a pregnancy registry be established.

In our analysis, the patients who used mifepristone alone had a lower rate of hemorrhage than those using mifepristone followed by misoprostol.

The FDA Adverse Event Reporting System is woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events. The reliance solely on interested parties to report, the large percentage of uncodable events, the redaction of critical clinical information unrelated to personally identifiable information, and the inadequacy of the reports highlight the need to overhaul the current AER System.

This analysis evaluated 3197 adverse events resulting from the use of mifepristone as an abortifacient and brought to light serious concerns about the safety requirements and care of women undergoing mifepristone abortion. Although complications may occur in the best of hands, and no medical procedure is without risks, safety measures must be employed to minimize these adverse outcomes. Women undergoing abortion should receive the same quality of informed consent and pre-procedural counseling that is standard of care prior to other medical treatment or surgery. It is imperative that women considering abortion be provided adequate and complete information and counseling on risks, advantages, disadvantages, and alternative options. Although there may be disagreements about the ethics of abortion, there must be total agreement that our patients—whether undergoing a medical abortion or otherwise—deserve the highest standard of medical care.

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Sexual Minorities who Reject an LGB Identity: Who Are They and Why Does It Matter?

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ABSTRACT: Although some persons with minority sexual orientations do not identify as lesbian, gay, or bisexual (LGB), Minority Stress Theory (Meyer, 2003) has largely been developed utilizing LGB-identified samples. We examined a sample ($n = 274$) of sexual minorities with diverse religious and sexual identity labels to determine if those rejecting versus adopting an LGB identity were different in terms of religious, sexual, relational, and health characteristics. Results suggested those who reject an LGB identity are more likely to be religiously active, full members of their church, and highly intrinsic and theologically conservative in their religious viewpoint. They further reported having slightly more lifetime heterosexual attractions, fantasies, and behaviors; greater internalized homonegativity; and being more interested in having children and a child-centered family life. They were also more likely to be single and celibate or in a heterosexual relationship. Contrary to expectations, these differences were not associated with health differences in depression, anxiety, and social flourishing. LGB-identi-

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fied participants did report higher life satisfaction than those rejecting an LGB identity, but this difference was not interpretively meaningful when considered in reference to population norms. We conclude with a discussion of the potential implications of our findings for research, legal and professional advocacy, and clinical care.

Keywords: **sexual identity, religion, health, LGBTQ, minority stress**

Although many sexual minorities adopt a lesbian, gay, bisexual (LGB) identity, some persons who experience same-sex attractions reject an LGB identity in favor of other descriptions for their sexuality, such as "same-sex attracted" or "mostly heterosexual" (Lefevor et al., 2020). Because research typically focuses on LGB-identified individuals, very little is known about those who reject an LGB identity. In this study, we seek to identify characteristics of this group and how these characteristics may distinguish them from sexual minorities who are LGB-identified. We also examine to what extent these groups differ on several health measures and close with a discussion about why our findings matter for this literature.

Implications of Minority Stress Theory for Rejecting an LGB Identity

Minority stress theory (MST) maintains that LGB persons experience stress associated with their stigmatized social status and this stress is responsible for their increased risk for psychological distress (Meyer, 2003). Meyer proposed a number of stress processes linked to LGB identity along a distal-proximal continuum. Distal stressors are defined as objective events, such as violence or overt acts of prejudice. Proximal stressors are defined as perceptions or appraisals of objective events, including hypervigilance or internalized stigma. The present study focuses on three core proximal stressors: expectations of rejection, concealment, and internalized homonegativity (IH). Research has indicated that each of these proximal stressors are associated with adverse mental health outcomes for sexual minorities in comparison to their heterosexual counterparts (Cohen et al., 2016; Newcomb & Mustanski, 2010; Pachankis et al., 2020). Each of these may also have implications for sexual minorities who do not identify as LGB.

Expectations of Rejection

Experiences of stigma and prejudice in one's interactions can result in anticipating future rejection and being sensitive and vigilant toward the interpersonal world (Feinstein et al., 2012). Following MST, sexual minorities may reject an LGB identity label to manage stigma and expectations of rejection in their environment. Heteronormative religious settings are a common example of where such sexual identity rejection may occur.

Concealment

Concealment is an internal psychological-stress process whereby individuals hide their stigmatized minority sexual identity due to feelings of guilt and shame and/or out of fear its disclosure would cause them harm (Meyer, 2003; Pachankis et al., 2020). Within this framework, sexual minorities who reject an LGB identity may do so to evade detection and potential negative ramifications in non-affirming environments. Such consequences might include loss of a social network, loss of social status, expulsion from a private school, and/or loss of church membership.

Internalized Homonegativity

Sexual minorities coping with stigma and prejudice may also internalize these experiences and the accompanying negative beliefs, a stress-inducing process called internalized homonegativity (IH) (Puckett et al., 2017; Szymanski et al., 2008). This internalization of negative beliefs may lead sexual minorities to reject an LGB identity. Certain faith or political communities may, for example, impart beliefs that the experience of same-sex attractions makes one morally deficient, inferior, or mentally ill.

Religious Exposure and Proximal Stressors

A significant body of research has found religion, and particularly conservative religion, to be associated with these proximal stressors. Generally, conservative or traditional religiosity has been related to more homonegative beliefs, greater sexual minority identity concealment, and higher levels of IH, all of which are in turn associated with poorer mental health outcomes (Crowell et al., 2015; Newcomb & Mustanski, 2010; Pachankis, et al. 2020; Sowe et al., 2014; Stern & Wright, 2017). However, this literature also largely relied upon LGB-identified samples and, as a consequence, may have limited validity for non-LGB-identified conservatively religious sexual minorities (Szymanski et al., 2008). For example, rejection of an LGB identity may limit exposure to proximal stressors within conservative religious communities and promote access to social connection within these groups, both of which could reduce associations with negative health outcomes.

Although Meyer (2003) theorized sexual minorities who did not adopt an LGB identity would not be subject to proximal stressors, to our knowledge this has not been tested among sexual minorities who reject an LGB identity. From our perspective, individuals experiencing same-sex attractions in a conservative religious setting may not be concealing a sexual identity, but certainly are concealing the presence of sexual attractions whose behavioral enactment would be strictly prohibited. This could promote fears of rejection and internalized negativity. Our study thus presumes these stressors are real for sexual minorities who reject an LGB identity, though further research with such a focus is certainly desirable.

Possibly motivated and undergirded by religious norms, rejection of an LGB identity would also appear to signal a lack of identity integration and self-acceptance, which is viewed in many sexual minority developmental models and LGB-affirmative therapies as the culmination of the coming out process (e.g., McCormick & Baldridge, 2019; Fassinger & Miller, 1996). The minority stress processes resulting in a disruption of LGB identity formation would be expected to result in mental health disparities between sexual minorities who have integrated their LGB identity as compared to those who have rejected it.

Although MST has been helpful in understanding the experiences of many sexual minorities, it was ultimately developed to describe the experiences of LGB-identified sexual minorities. As such, it may have limited applicability to sexual minorities who reject an LGB identity, particularly those in conservative religious contexts. The present study examines sexual minorities who reject an LGB sexual identity label in comparison to those who are LGB identified. In light of the research on minority stress and mental health outcomes, we sought to (a) understand who rejects a sexual minority identity status and (b) determine if this rejection is associated with measures of mental health.

Method

Survey Design

Participants were asked to take part in a survey that was designed to identify important aspects of life and relationships for those who experience (or have experienced) same-sex attractions (SSA) and identify as LGB, heterosexual, other sexual identities, or who reject a label, and were involved in one of four relationship options (i.e., single and celibate; single and non-celibate; heterosexual, mixed-orientation relationship; same-sex relationship). Participants completed the survey through a website designed for the survey (4OptionsSurvey.com). A description of the survey can be found in Lefevor et al. (2019).

Data Collection and Recruitment

We obtained approval from the Idaho State Institutional Review Board prior to commencing this study. Data collection occurred over a 10-month period from September 2016 to June 2017. This involved invitations through (a) news media in Utah; (b) email lists, Facebook groups, and conventions; (c) psychological associations and support networks; and (d) mental health providers. Organizations and networks utilized for recruitment ranged from those religiously and/or conservative oriented (e.g., North Star, Alliance for Therapeutic Choice and Scientific Integrity, People Can Change) to those formally LGB-affirming (e.g., American Psychological Association's Society for the Psychological Study of Sexual Orientation and Gender Diversity, the LGBTQ-affirmative Psychotherapist Guild of Utah, and the National Association for Social Work). Complete details about participant recruitment can be found in Lefevor et al. (2019). The present study was conducted mostly by individuals who have experienced SSA or identify as

LGB. In addition, some members of the research team hold leadership roles in conservative organizations such as North Star and The Alliance for Therapeutic Choice and Scientific Integity. This representation may have encouraged non-LGB-identified participants to believe their perspectives would be represented and understood. Indeed, 120 (43.8%) participants reported rejecting an LGB identity and 79 (28.8%) participants identified as theologically conservative.

To be included in analyses, participants must have (a) been at least 18 years of age, (b) experienced SSA at some point in their life, (c) identified their relationship status, and (d) completed the first two sections of the survey, which took approximately one hour to complete. More details about recruitment and makeup of the full sample can be obtained from Lefevor et al. (2019).

Participants

A total of 1499 respondents completed all mandatory questions. Our focus for this study was on participants who had never identified as Mormon and rejected or adopted an LGB identity ($n = 274$) as Mormon participants have been analyzed elsewhere (Lefevor et al., 2020). The average age of these participants was 42.3 ($SD = 14.8$). In terms of gender, 62 participants identified as women, 209 as men, and 14 used other descriptors (e.g., transman, gender fluid, genderqueer). Our sample was primarily White ($n = 227$) and educated, with 75.2% ($n = 206$) earning at least a bachelor's degree.

Measures

The survey included both measures specifically created for this study as well as preexisting measures and was designed to provide data to inform several studies. The present research incorporated the variables described below. Differences in sample sizes for some of these variables occurred due to the exclusion of "not applicable" responses when it was inappropriate to incorporate these responses into the measure.

Demographics

We included single item measures of age, education (a 6-point Likert scale from "*Less than high school degree*" to "*Graduate degree*"), race (0 = White, 1 = All others), and gender (1 = Female, 2 = Male, 3 = Others). The LGB and non-LGB participants did not differ in level of education or racial distribution, but the non-LGB group was older ($M = 44.98$, $SD = 14.64$) than the LGB group ($M = 39.9$, $SD = 14.52$) ($t(272) = 2.87$, $p < .01$, $d = .35$). In addition, the LGB-identified group contained more women ($n = 39$) than the non-LGB identified ($n = 18$) ($X^2(2) = 9.98$, $p < .007$, Cramer's $V = .19$).

Religiousness

We utilized four common indicators of religiousness. Church/religious activity was measured on a 5-point Likert scale from 1 = *More than once per week* to 5 = *Stopped attending/not applicable*. This variable was transformed so that higher scores would in-

dicate greater religious activity. Current church/religious statuses examined were "full member," alienated from membership (e.g., probation, disfellowshipped, excommunicated, resigned), and "disinterested/not applicable." Many options for religious views were offered to participants, and categories employed were (a) "theologically conservative, traditional, or orthodox"; (b) "theological moderate"; (c) "theological liberal/progressive"; (d) "other religious views" (e.g., "theologically heterodox" and "spiritual but not religious"); and (e) "non-religious or anti-religious." Intrinsic Religiosity (IR) was measured by the statement, "My whole approach to life is based on my religion/spirituality" (Gorsuch & McPherson, 1989). This item utilized a 7-point Likert scale format from 1 = *Strongly disagree* to 7 = *Strongly agree*.

Relationships

We assessed relationship contexts using four measures. Participants indicated whether they were (a) single and celibate; (b) single and not celibate; (c) in a heterosexual, mixed-orientation relationship; or (d) in a same-sex relationship. Participants' history of heterosexual marriage was assessed with the question, "Have you ever been in a heterosexual marriage?", with response options of (a) currently in a heterosexual marriage, (b) divorced or separated, (c) widowed, (d) never, and (e) other. Due to low frequencies, widowed participants were included in the "other" category. Participants were also asked about the importance they place on having children and living a child-centered life now or in the future. Responses ranged from 1 = *Not important to me* to 4 = *Very important to me*. Degree of social support was assessed with the question, "I meet my needs for connection, intimacy, and mutual understanding" rated on a 7-point Likert scale anchored by 1 = *Never* to 7 = *Always*.

Sexuality

Sexuality-related variables included Kinsey (Kinsey et al., 1948) lifetime ratings of sexual behaviors, attractions, and fantasies utilizing a 7-point Likert scale ranging from 1 = *Exclusively heterosexual with no homosexual* to 7 = *Exclusively homosexual with no heterosexual*. Two participants who reported no lifetime experience of same-sex attractions, behaviors, and fantasies were removed from the sample before our analyses. IH was assessed using the three-item internalized homonegativity subscale from the Lesbian, Gay, and Bisexual Identity Scale (Mohr & Kendra, 2011). The authors report an internal consistency of .86 and a test-retest reliability of .92. Cronbach's alpha for the present study was .90. This scale is in line with the original conceptualization of IH (Puckett et al., 2017), including the item, "If it were possible, I would choose to be straight." Total scores could range from 3 to 21, with higher scores signaling greater IH. Participants also indicated the degree of conflict between religious and sexual identities with the single item, "I feel resolved about my sexuality and religious issues." IH and identity resolution were both measured on a 7-point Likert scale ranging from 1 = *Strongly disagree* to 7 = *Strongly agree*.

Sexual Identity Labeling

Participants were asked about their current sexual identity and given 28 options from which to choose. They also indicated their degree of rejection of an LGB identity or acceptance of it through the question, "I am open/out about my rejection of the gay/lesbian/bisexual identity (mark N/A if you identify as gay/lesbian/bisexual)." Degree of openness about LGB identity rejection ranged from 1 = *Never* to 7 = *Always*. Participants who indicated rejection of an LGB identity regardless of their degree of outness about it were grouped (n = 120) and compared with participants identifying as LGB (n = 154), resulting in a final sample of 274.

Not surprisingly, there were significant differences between the groups regarding their current sexual identity ($X^2(17) = 103.68$, $p < .001$, Cramer's $V = .62$. Despite indicating that they rejected an LGB identity, 17 participants also reported an LGB identity earlier in the survey. After deliberation, we decided to include these individuals with those who rejected an LGB identity.

Health Indicators

Depression. Current depression was measured using the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001). The PHQ-9 has good concurrent validity with the Short Form-20 (SF-20) and diagnosis of major depressive disorder (Kroenke et al., 2001). Total scores could range from 4 to 36 with higher scores reflecting greater depression. Cronbach's alpha for the present study was .91.

Anxiety. Current anxiety was measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale (Spitzer et al., 2006). The GAD-7 has good concurrent validity with the SF-20 and diagnosis of generalized anxiety disorder (Spitzer et al., 2006). Total scores could range from 4 to 28 with higher scores indicating greater anxiety. Cronbach's alpha for the present study was .91.

Flourishing. Psychosocial flourishing was measured using the Flourishing Scale (Diener et al., 2009), an 8-item measure of self-perceived success in areas such as relationships, purpose, and optimism rated on a 7-point Likert scale with anchors of 1 = *Strongly disagree* to 7 = *Strongly agree*. Total flourishing scores could range from 8 to 56 with higher scores indicating greater flourishing. The Flourishing Scale is psychometrically validated and is comparable to other measures of psychosocial well-being. Cronbach's alpha for this present study was .93.

Life Satisfaction. Life satisfaction was assessed with the five-item Satisfaction with Life Scale (SWLS; Diener et al., 1985). Participants indicated agreement with statements on a 7-point Likert scale ranging from 1 = *Strongly disagree* to 7 = *Strongly agree*. Total life satisfaction scores could range from 5 to 35 with higher scores signaling greater life satisfaction. Cronbach's alpha for the present study was .89.

Data Analysis. All analyses were conducted using SPSS Statistics 25. Univariate analyses supported the linearity and normality of all our continuous variables. All variables were within the acceptable range with skewness less than 2 and kurtosis less

than 5 (West et al., 1995). These impressions were confirmed by examination of residuals. Independent-samples *t*-tests were used for group comparisons on continuous variables. Cohen's *d* was obtained as the effect size statistic and interpreted according to his recommendations (Cohen, 1992). Chi-square statistics were employed for analyses of comparisons for nominal variables. Due to the number of comparisons, we used an alpha of .01 to control for Type I error.

Results

Univariate statistics and participant characteristics for the full sample are presented in Table 1. Results for group comparisons between LGB-identified and LGB-rejecting participants are examined below.

Religion, Relationships, and Sexuality

Tables 2 and 3 display the significant findings for differences between participants who adopt versus reject an LGB identity as pertains to religiousness, relationships, and sexuality. Religiously, sexual minority individuals who rejected an LGB identity tended to be more active in and full members of their church as well as more highly intrinsic and conservative in their religious viewpoint than those who identified as LGB, with effect sizes in the medium to large range. In terms of the relationship variables, those rejecting an LGB identity tended to place a greater emphasis on having family and children and were more likely to be single and celibate than participants who identified as LGB, with effect sizes in the medium range. The groups did not differ in the degree they felt their needs for connection and intimacy were being met, though there was a trend in the direction of LGB participants ($M = 4.91$, $SD = 1.80$) feeling more connected than those who rejected an LGB identity ($M = 4.33$, $SD = 2.01$)($X^2(269) = 2.47$, $p = .013$, $d = .30$). There was not a significant difference in participants' history of involvement in a heterosexual marriage/relationship, although there was a trend suggesting that those rejecting an LGB identity may be more likely to have been involved in a heterosexual marriage/relationship than LGB participants ($X^2(3) = 9.61$, $p < .05$, Cramer's $V = .19$).

Regarding sexuality, participants who rejected an LGB identity reported greater IH and lower Kinsey lifetime attraction ratings (i.e., more heterosexual attractions, fantasies, and behaviors) than the LGB participants, with effect sizes being large for IH and medium for the Kinsey ratings. In post hoc analyses, we noted within the LGB-identified group the association between IH and depression ($r(154) = .21$, $p = .01$) diminished slightly when controlling for religious activity ($r(154) = .18$, $p < .02$). However, among participants rejecting an LGB identity, the association between IH and depression ($r(120) = .33$, $p < .001$) *increased* when religious activity was controlled ($r(120) = .46$, $p < .001$), suggesting IH and religious activity may operate differently for these groups in relation to health outcomes. The Kinsey ratings indicate that participants who reject an LGB identity label reported on average somewhat more heterosexual attractions, though both groups described themselves as predominantly experiencing same-sex attractions (SSA).

Table 1. Participant Characteristics.

Characteristic	*M*	*SD*	Characteristic	*M*	*SD*
Age	42.11	14.72	Importance of Children	2.35	1.41
Education	4.89	1.24	Internalized Homonegativity	9.77	5.96
Religious Activity	1.91	1.78	Depression	14.80	5.58
Intrinsic Religiousness	5.22	1.96	Anxiety	12.22	5.05
Kinsey Lifetime Rating	5.50	1.52	Psychosocial Flourishing	46.82	8.20
Identity Resolution	5.45	1.72	Life Satisfaction	23.28	7.00

Characteristic	*n*	%	Characteristic	*n*	%
Religious Affiliation			Sexual Identity		
None/Unaffiliated	93	33.9	Lesbian or Gay	96	35.0
Catholic	40	14.6	Same-Sex/ Gender Attracted	41	15.0
Evangelical Protestant	32	11.7	Heterosexual with SSA	30	10.9
Baptist	15	5.5	No Option/ More than One Applies	23	8.4
Jehovah's Witness	12	4.4	Bisexual	13	4.7
Judaism	12	4.4	Homosexual	13	4.7
Methodist	11	4.0	Heterosexual/Straight	12	4.4
Pentecostal	11	4.0	Do Not Use a Label	12	4.4
Exploring Options	11	4.0	Queer	8	2.9
Other	37	13.5	Other	26	9.5
Religious Affiliation			Race		
Theology Conservative	79	28.8	White/Caucasian	227	82.8
Spiritual/Not Religious	36	13.1	Multi-Ethnic/None Apply	13	4.7
Theology Heterodox	28	10.2	Latina(o)/Hispanic/ American	12	4.4
Atheist	25	9.1	Black/African-American	9	3.3
Theology Liberal	22	8.0	Middle Eastern/ M.E. American	5	1.8
Theology Moderate	20	7.3	Asian/Asian American	4	1.5
Non-Religious	17	6.2	South Asian	3	1.1
Agnostic	15	5.5	Native American/ American Indian	1	.4
Others	32	11.8			

Table 1. (*Continued*).

Characteristic	*n*	%	Characteristic	*n*	%
Heterosexual Marriage Status			Relationship Status		
Never Married	194	70.8	Single and Celibate	83	30.3
Currently Married	47	17.2	Same-Sex Relationship/ Marriage	78	28.5
Divorced/Separated	24	8.8	Single, Not Celibate	59	21.5
Other	5	1.8	Heterosexual Relation/ Marriage	54	19.7
Widowed	4	1.5			
Current Church/ Religious Status					
Full Member	133	48.5			
Not Applicable	63	23.0			
Disinterested	49	17.9			
Resigned	20	7.3			
Plan to Leave	4	1.5			
Formal Probation	3	1.1			
Excommunicated	2	.7			

Note. $N = 274$ except for Intrinsic Religiousness ($N = 233$), Kinsey Ratings ($N = 264$), Identity Resolution ($N = 235$), and Importance of Children ($N = 262$). Smaller *N*'s due to *Not Applicable* responses being excluded.

Table 2. Significant Group Differences Between Participants Identifying as LGB and Those Rejecting an LGB Identity.

	LGB			Reject LGB				
Variable	***n***	***M***	***SD***	***n***	***M***	***SD***	***t***	**Cohen's *d***
Religious Activity	154	1.38	1.70	120	2.58	1.64	−5.88**	.72
Intrinsic Religiousness	116	4.68	2.04	106	5.80	1.70	−4.67**	.60
Children/Family Important	154	2.10	1.32	120	2.68	1.45	−3.40**	.42
Kinsey Lifetime Attraction	152	5.82	1.33	112	5.06	1.64	4.02**	.51
Internalized Homonegativity	154	7.58	5.05	120	12.58	5.87	−7.42**	.91
Life Satisfaction	154	24.29	6.94	120	21.98	6.89	2.75*	.33

Key: * $p < .01$. ** $p < .001$. Unequal variances not assumed for Intrinsic Religiousness, Children/Family Important, Kinsey Rating, and Internalized Homonegativity.

Table 3. Significant Frequency Differences Between Participants Identifying as LGB and Those Rejecting an LGB Identity.

Variable	Category	% LGB	% Reject LGB	X^2	Cramer's *V*
Religious Viewpoint	Conservative	13.0%	49.2%	50.50*	.43
	Moderate	5.2%	10.0%		
	Liberal/Progressive	12.3%	5.0%		
	Other	40.3%	20.0%		
	Non- or Anti-Religious	31.2%	15.8%		
Church Status	Full Member	33.1%	68.3%	40.23*	.38
	Alienated from Church	16.0%	3.3%		
	Not Interested/Applicable	50.6%	28.3%		
Relationship Status	Single & Celibate	18.8%	45.0%	41.90*	.39
	Single Not Celibate	26.6%	15.0%		
	Mixed Orientation Relationship	14.3%	26.7%		
	Same-Sex Relationship	40.3%	13.3%		

Key: * $p < .001$.

Participants who reject an LGB identity ($M = 5.40$, $SD = 1.81$) did not differ from the LGB group ($M = 5.50$, $SD = 1.65$) in terms of the degree of resolution of conflict between their religious and sexual identities ($X^2(232) = .48$, $p = .63$, $d = .06$). On average, both groups reported moderate agreement with having resolved these issues.

Health Indicators

For the most part, health indicators were not different between sexual minorities who adopted or rejected an LGB identity. The LGB-identified participants and those rejecting an LGB identity label reported similar levels of depression ($M = 14.36$, $SD = 5.39$ vs. $M = 15.37$, $SD = 5.79$, respectively)($t(272) = -1.49$, $p = .14$, $d = .18$), anxiety ($M = 12.05$, $SD = 5.14$ vs. $M = 12.47$, $SD = 4.99$)($t(272) = -.67$, $p = .50$, $d = .08$), and flourishing ($M = 47.37$, $SD = 7.72$ vs $M = 46.13$, $SD = 8.75$)($t(272) = 1.25$, $p = .21$, $d = .15$). However, we did find that participants identifying as LGB reported greater life satisfaction than those rejecting an LGB identity, with a medium effect size.

As a check on our findings, we reran our analyses after removing the 17 participants who indicated an LGB identity earlier in the survey and later indicted rejecting such an identity. The removal of these individuals did not substantially alter our results. In fact, subsequent effect sizes increased modestly, although their strength did not change in terms of conventional interpretive guidelines. These may be individuals less dogmatic about their rejection of an LGB identity, but whatever the reasons for their manner of responding, their inclusion with other participants who reject an LGB identity appears empirically justifiable.

Discussion

We examined a theologically diverse sample of sexual minorities to determine how those who reject an LGB identity may differ from those who have adopted an LGB identity and how the two groups compare in terms of health indicators. Our findings are generally consistent with a recent study on Mormon sexual minorities (Lefevor et al., 2020) and suggest that significant differences exist between the two groups; however, these differences do not appear to translate into health disparities.

Who Rejects an LGB Identity?

Participants who rejected an LGB label were significantly more conservatively religious than LGB-identified participants. They were also more likely to be single and not sexually active or in a heterosexual relationship and place a greater emphasis on raising children than those identifying as LGB. These values and relational choices likely reflect the heteronormative environment of conservative religious communities. Participants who rejected an LGB label also reported on average somewhat more heterosexual attractions, fantasies, and behaviors than LGB-identified participants, though both groups described themselves as predominantly experiencing same-sex attractions, fantasies, and behaviors. These sexual experiences may undergird the difference between these groups in their sexual identification and their involvement in and aspirations for heterosexual marriage and a child-centered family life. Nonetheless, we note that both groups indicated a primarily same-sex sexual orientation.

We found also that both groups reported feeling moderately resolved about any conflicts between their sexuality and religious issues. Both groups further reported similar degrees of social support and age. These findings contrast with expectations that those rejecting an LGB identity may be less developed in their sexual identity than LGB individuals and hence be expected to eventually adopt an LGB identity (Fassinger & Miller, 1996). Rather, it seems more likely the rejection of an LGB identity by these sexual minorities reflects the congruence between their conservatively religious values; their sexual experiences; and their ability to meet needs for connection, intimacy, and mutual understanding within their conservatively religious community (Barringer & Gay, 2017).

In keeping with our view that religiously active sexual minorities who reject an LGB identity are still subject to the proximal stressors of Minority Stress Theory, we found IH to be significantly greater among participants who rejected an LGB identity than for those LGB identified. However, in contrast to our expectations, for the most part, this was not associated with worse reported health (see also Barnes & Meyer, 2012). This may be due to the buffering effects on minority stress processes of social support and connection within religious communities (Barringer & Gay, 2017). Exposure to proximal stressors within conservative religious communities may be further mitigated by the rejection of an LGB identity, which in turn could reduce associations with negative health outcomes. Additionally, it is possible among some of those rejecting an LGB identity that our measure of IH, which prioritizes a heterosexual identity, may reflect

principled religious conviction more than health-diminishing shame or self-loathing (Hallman et al., 2018).

We did not find that participants who rejected an LGB identity had significantly worse levels of depression, anxiety, and psychosocial flourishing than those who were LGB identified. Assuming sexual minorities who reject an LGB identity are indeed subject to proximal sexual minority stressors, this seems at odds with minority stress and sexual identity theories that assume adoption of an LGB identity is the healthiest pathway of sexual minority identity development. This plausibly could be the result of the underrepresentation in research of sexual minorities who reject an LGB identity or are otherwise living within conservatively religious communities, a problem we discuss below. Nevertheless, these participants did report less life satisfaction than LGB-identified participants. This finding suggests that real stresses remain for sexual minorities who are active in conservative religious environments that may not be completely mitigated by the social capital available within these communities. No doubt leaders and members within these religious traditions can do more to promote emotional and relational thriving among sexual minorities in their communities.

It is also important to situate contextually the health findings within population norms. Means for both groups were in the moderately severe range (i.e., 15-20) for depression (Kronke et al., 2001) and in the moderate clinical range (i.e., 10-14) for anxiety (Spitzer et al., 2006). Despite these health findings, results for psychosocial flourishing indicated both groups were experiencing slightly above average levels of flourishing (Diener et al., 2009). Life satisfaction was slightly below the non-clinical sample average (i.e., 25; Diener et al., 1985) for participants rejecting an LGB identity, whereas the LGB-identified participants reported average life satisfaction levels. However, both groups are classifiable within the "slightly satisfied" range (Pavot & Diener, 1993); therefore, this difference may not be interpretively meaningful. These findings may suggest that, regardless of identity choice and although minority stress negatively impacts the emotional health of these sexual minorities, both groups find ways to live equally flourishing and satisfying lives within their respective conservatively religious or LGB communities. Minority stress processes not specific to conservatively religious environments may be dominant in the depression and anxiety findings; alternatively, sexual orientation minority stresses unique to LGB communities may be roughly as harmful to sexual minorities as minority stresses deriving from conservatively religious contexts. It is also possible non-sexual orientation related stress processes common to both groups are important in explaining the emotional distress of our sample. Further research is needed to clarify these important questions.

Implications for Research, Advocacy, and Clinical Care

Our findings have several implications for understanding sexual minorities who reject an LGB identity. We briefly address three intersecting areas of concern related to research and advocacy, clinical care, and the need for profession-wide ideological diversity.

Our findings for sexual minorities who reject an LGB identity seem to go against the scholarly consensus and conventional wisdom pertaining to those who experience SSA but remain in conservative religious faith communities. Contrary to expectations that severe minority stresses within heteronormative religious contexts and a concomitant disrupted sexual identity development would be associated with greater adverse health, we found no significant or interpretively meaningful health differences between those rejecting or adopting an LGB identity. This may have been a function of sociopolitically diversifying our research team to gain the trust of and have access to conservative sexual minority networks that have large numbers of individuals who reject an LGB identity. We suspect our findings would not be so surprising if research in this area was regularly conducted outside the LGB networks and venues more easily accessed by researchers whose values and beliefs align with those they study. To put it another way, when studies utilize LGB self-identity as the sexual minority inclusion criterion, they exclude those sexual minorities rejecting an LGB identity by definition and render these individuals invisible.

This potentially serious limitation of the research literature has implications for legal and mental health advocacy, particularly where legislative and policy initiatives impact sexual minorities and their conservative religious communities (Rosik, 2017). Caution should be exercised not to assume theories and constructs derived from LGB samples can be easily generalized to sexual minorities who do not share such an identity (Lefevor et al., 2020). Similarly, using studies limited to or dominated by LGB-identified persons alienated from or uninterested in traditional faith communities (e.g., Dehlin et al., 2015; Hamilton & Gross, 2013; Ryan et al., 2020; Sowe, Brown et al., 2014; Sowe, Taylor et al., 2017) as a basis for laws or advocacy efforts that impact sexual minorities in traditional religious settings may be a dubious practice (e.g., advocating the curtailment of religious freedoms to promote LGB well-being; Sowe, Taylor, et al., 2017). Legal opinions as well as official pronunciations and clinical guidance from professional associations in this arena need to be grounded in population-based samples able to identify sexual minorities who reject LGB labels or samples purposefully recruiting sexual minorities not LGB identified. Furthermore, mental health professionals encountering sexual minority clients who are (or are not) embedded within conservative religious communities should not assume their rejection of an LGB identity label inhibits their ability to live healthy, meaningful, and satisfying lives.

At the broadest level, our findings highlight the value of ideological diversity for developing a more comprehensive understanding of sexual minorities. When legal and mental health associations become too tribal (Clark & Winegard, 2020), there is a risk certain groups and perspectives will be overlooked, as may have been the case with sexual minorities who reject an LGB identity. As Chambers et al. (2013) warned, "To the extent that social scientists operate under one set of assumptions and values, and fail to recognize important alternatives, their scientific conclusions and social-policy recommendations are likely to be tainted" (p. 148). We hope our experience with an ideologically diverse research team exemplifies the benefits of such an endeavor and

encourages legal and mental health professionals to prioritize sociopolitical diversity as a diversity dimension in their research and advocacy.

Limitations

Some limitations of our study should be noted. The study's cross-sectional nature does not allow for a determination of causation in our findings. It is possible that participant characteristics between sexual minorities rejecting versus adopting an LGB identity promote well-being and do so in different ways. It is also possible preexisting levels of well-being lead to specific differences in certain participant characteristics (e.g., less depression enables greater religious activity among those rejecting LGB identity and less religious activity among those who identify as LGB).

Many of our variables were single-item measures, which is common for exploratory research but precludes our ability to establish their psychometric properties. This limitation also suggests caution in interpreting our findings, although single-item measures are common in the sexual orientation literature and have not prevented other studies from being widely cited (e.g., Dehlin et al., 2015; Ryan et al., 2020).

Our sample consisted primarily of white men and hence may not generalize to women and racial minorities. Finally, we utilized theological identification to discern conservative faith communities among participants. Although this assumption is sensible, it is possible religious viewpoint may not be an exact indicator of the degree to which a participant's religious community is affirming or rejecting of an LGB identity.

Conclusion

We examined a sample of sexual minorities with diverse religious and sexual identity labels to determine if those rejecting versus adopting an LGB identity were different in terms of religious, sexual, relational, and health characteristics. Results suggested those who reject an LGB identity are more likely to be religiously active, hold full membership in their church, and be highly intrinsic and theologically conservative in their religious viewpoint. They further report slightly more heterosexual attractions and behaviors, greater internalized homonegativity, and more interest in raising children. They also were more likely to be single and celibate or in a heterosexual relationship. Contrary to our expectations from minority stress and sexual identity development theories, these differences were not associated with differences in experiences of depression, anxiety, and social flourishing, nor were they related to interpretively meaningful differences in life satisfaction. These findings seem to be at odds with conventional wisdom and underscore the importance of pursuing sociopolitical diversity among researchers and the populations they study as well as its value for ensuring appropriate legal advocacy and clinical care.

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Value-Based Costing of Anti-Cancer Drugs: An Ethical Perspective Grounded in Catholic Teachings on Human Dignity and the Common Good

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ABSTRACT: Americans have benefited from a declining cancer incidence and improving prognosis over the past two decades, during which time rising prices for anti-cancer drugs have proportionally outstripped rising expenditures for overall cancer care and total national health expenditures. To meet the economic challenges, remedies have been proposed to base compensation on relative survival measurements perhaps taking into account associated drug toxicities, disabilities, and disease progression. While there are advantages for knowing the economic costs determined from so-called, "value-based" methodologies, it must be recognized that the measured values are impersonal, incomplete, and always biased. This article examines value-based costing of anti-cancer drugs in an individual and societal framework and advocates grounding decisions regarding cancer care and pharmaceutical costs on the ethical principles of human dignity and the common good.

With annual national healthcare expenditures (NHE) in the United States of America (USA) at $3.5 trillion, accounting for over 17.9% of gross national product (GDP), and projected to grow at an average annual rate of 5.5%, there is grave con-

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cern over how annual NHE at these levels can be sustained with average annual GDP growth rates of 3.2% since 1948.[1] The national expenditures for cancer care, alone, exceeds $150 billion per year; assuming recent cancer incidence, survival trends, growth of an aging population and the rising costs of drugs and technology, this could reach more than $200 billion in 2020.[2] The good news is that cancer incidence in the USA is declining, neoplastic diseases are being detected at earlier stages, and survivals are improving; but the expense to treat even the most common cancers has been increasing over the past two decades.[3]

Simultaneously, the NHE for prescription drugs have more than doubled since 2000.[4] Because prescription drugs constitute some 10% of the expenditures for cancer care, by 2020 our national expenditures for cancer chemotherapy, alone, could be well over $20 billion with the increasing use of newer anti-cancer drugs.[5] Individual cancer

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patients can already face expenses for prescription drugs which exceed $75,000 per year of life gained, even with currently standard anti-neoplastic chemotherapy.[6] And prescription drug prices continue to soar for newly developed pharmaceuticals. The mean annual incremental difference in chemotherapy costs between standard anti-cancer regimens and novel new anti-cancer drugs was calculated to increase from $30,000 in 2006 to more than $130,000 in 2015.[7] Today, the addition of recently released anti-cancer drugs to older regimens of proven effectiveness, whether to complement or to be used sequentially, may add just a few weeks to several months average overall survival with expenditures of $100,000 to more than $450,000 per year of life gained.[8]

To address the accelerating costs for life-extending and potentially life-saving anti-cancer drugs, several quantitative methodologies have been proposed, which would base the pricing of pharmaceuticals on values predetermined by third parties with little or no consideration of values that patients and the public may hold more dearly. So-called "value-based" pricing or costing strategies evoke serious questions concerning patients' access to cancer care and distributive justice. This article examines value-based costing of anti-cancer drugs in an individual and societal framework and advocates grounding decisions regarding cancer care and costs on the ethical principles of human dignity and the common good.

Pricing, Costs, and Values

When speaking of healthcare and pharmaceutical expenses or expenditures in ordinary parlance and in scholarly conversations, essays, and reports, the words "price" and "cost" are often interchangeable.[9] For the present exposition, the term "price" is defined as

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[9] Allan G. M., J. Lexchin, and N. Wiebe. 2007. Physician awareness of drug cost: A systematic review. *PLoS Medicine* 4(9): e283. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040283 (accessed May 4, 2017); Bach 2014a, *loc. cit*.; Bach, P. B. 2014b. Indication-specific pricing for cancer drugs. *Journal of the American Medical Association* 312(16): 1629-1630; Bach, P. B. 2015. A new way to define value in drug pricing. *Harvard Business Review.* October 6. https://hbr.org/2015/10/a-new-way-to-define-value-in-drug-pricing (accessed May 18, 2017); Bach, P. B., and S. D. Pearson. 2015.

a quantity of money or equivalent exchanged or exchangeable for a quantity of goods and/or services and distinguished from "cost," which, herein, is defined as either or both an intangible or a tangible outlay or foregoing, that could of course include monetary price.

Reasons given for high and rising costs for cancer care and prices for anti-cancer drugs are multiple.[10] Market prices for anti-cancer drugs are inconsistent and do not necessarily reflect the resources that are expended in developing, producing, and distributing them.[11] Prices on the retail market may be disproportionate to various wholesale prices negotiated with private drug and insurance plans.[12] Some authors

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Payer and policy maker steps to support value-based pricing for drugs. *Journal of the American Medical Association* 314(23): 2503-2504; Bach, P. B., L. B. Saltz, and R. E. Wittes. 2012. In cancer care, cost matters. *The New York Times*. October 14. http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-an-11000-a-month-cancer-drug.html (accessed January 30, 2017); Elkins 2015, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Howard et al. 2016, *loc. cit.*; Kesselheim, A. S., J. Avorn, and A. Sarpatwari. 2016. The high cost of prescription drugs in the United States. Origins and prospects for reform. *Journal of the American Medical Association* 316(8): 858-871; Lee, T. T., A. R. Gluck, and G. Curfman. 2016. The politics of Medicare and drug-price negotiation (Updated October 2016). *HealthAffairsBlog*. September 19. https://healthaffairs.org/blog/2016/09/19/the-politics-of-medicare-and-drug-price-negotiation/ (accessed January 17, 2017); Lakdawalla, D. N., J. A. Romley, Y. Sanchez, J. R. Maclean, J. R. Penrod, and T. Philipson. 2012. How cancer patients value hope and the implications for cost-effectiveness assessments. *Health Affairs* 31(4): 676-682; Mariotto et al. *loc. cit.*; Pfister, D. G. 2013. The just price of cancer drugs and the growing cost of cancer care: Oncologists need to be part of the solution. *Journal of Clinical Oncology* 31(28): 3487-3489; Prasad et al. 2017, *loc. cit.*, Rubin, R. 2016. Value pricing for drugs: Whose value, what price? *HealthAffairsBlog* March 28. https://healthaffairs.org/blog/2016/03/28/value-pricing-for-drugs-whose-value-what-price/ (accessed November 22, 2016); Salas-Vega and Mossialos 2016, *loc. cit.*; Siddiqui and Rajkumar 2012, *loc. cit.*; Society of Gynecologic Oncology. 2016. *Addressing the High Cost of Drugs for Oncology Patients: A National Priority*. Washington, DC: Society of Gynecologic Oncology. https://www.sgo.org/public /addressing-the-high-cost-of-drugs-for-oncology-patients/ (accessed May 3, 2017).

[10] Bach, P. B. 2009. Limits on Medicare's ability to control rising spending on cancer drugs. *New England Journal of Medicine* 360(6): 626-633. Bender 2018, *loc. cit.*; Brock, D. W. 2010. Ethical and value issues in insurance coverage for cancer treatment. *The Oncologist* (suppl 1): 36-42. https://theoncologist.alphamedpress.org/content/15/suppl_1/36.full.pdf+html (accessed January 7, 2017); Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Love, J. 2017. Perspectives on cancer drug development costs in JAMA. *Bill of Health: Examining the Intersection of Health, Law, Biotechnology, and Bioethics*. Petrie Flom Center. Harvard Law School. September 13. https://blog.petrieflom.law.harvard.edu/2017/09/13/perspectives-on-cancer-drug-development-costs-in-jama/ (accessed January 4., 2019); Pfister 2013, *loc. cit*. Prasad et al. 2017, *loc. cit*.

[11] Anderson, R. 2014. Pharmaceutical industry gets high on fat profits. *BBC News*. November 6. http://www.bbc.com/news/business-28212223 (accessed May 5, 2017); Belk, D., and P. Belk. 2017. The pharmaceutical industry (including an analysis of the financial records of 12 major pharmaceutical companies from 2003-2015). *True Cost of Health-Care* http://truecostof healthcare.net/the_pharmaceutical_industry/ (accessed May 5, 2017); Bender 2018, *loc. cit.*; Prasad et al. 2017, *loc. cit*.

[12] DeAngelis, C. D. 2016. Big pharma profits and the public loses. *The Milbank Quarterly* 94(1): 30-33. https://www.ncbi.nlm.nih.gov/pmc/articles/pdf/MILQ-94-030.pdf (accessed May 5, 2017); Howard et al. 2015, *loc. cit.*; Reinhardt, U. E. 2016. Mylan's CEO a villain? Depends on your preferred brand of capitalism. *HealthAffairsBlog*. September 6. https://healthaffairs.org/blog/2016/09/06/mylans-ceo-a-villain-depends-on-your-preferred-brand-of-capitalism/ (accessed May 5, 2017).

have attributed the rising costs for anti-cancer drugs in the USA to a major shift toward prescribing newer, more expensive, branded drugs introduced during the past decade.[13] The facts are that the use of both generic and branded anti-cancer drugs is increasing in most countries and so are the overall expenditures for chemotherapy.[14] While a recent analysis of international data showed that an increase in the sales volume of branded anti-cancer drugs between 2004 and 2014 was associated with higher national expenditures for anti-cancer drugs overall, the use of generic anti-cancer drugs in the USA was significantly greater and the use of branded drugs in the USA was lower than in Canada and Europe.[15] But expenditures for both generic and branded anti-cancer drugs were significantly more in the USA than in other countries.[16]

The costs involved in research, testing, and bringing new drugs to market are enormous, and so can be the risks. Studies done over the past decade estimate that drug companies invested from $1.2 billion to over $2.8 billion for research and rigorous clinical trials per pharmaceutical agent which ultimately was approved by the Federal Drug Administration (FDA).[17, 18]

In aggregate, the pharmaceutical industry was reported to spend some $50 billion in just one year for research and development.[19] Though the patent life for a drug is 20 years from the date of filing, less than 19% of drugs that enter approximately eight years of clinical trials will receive FDA approval, after which the actual marketing of anti-cancer drugs is often fewer than ten years.[20] Then, on average only three in ten new

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[13] Bender 2018, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Zafar, S. Y. 2016. Financial toxicity of cancer care: It's time to intervene. *Journal of the National Cancer Institute* 108(5): djv370. https://academic.oup.com/jnci/article-lookup/doi/10.1093/jnci/djv370 (accessed January 10, 2017).

[14] Salas-Vega and Mossialos 2016, *loc. cit.*

[15] *Ibid.*

[16] *Ibid.*

[17] DiMasi, J. A., and H. G. Grabowski. 2007. The cost of biopharmaceutical R&D: Is biotech different? *Managerial and Decision Economics* 28: 469-479; DiMasi, J. A., H. G. Grabowski, and R. W. Hansen. 2016. Innovation in the pharmaceutical industry: New estimates of R & D costs. *Journal of Health Economics* 47(May): 20-33; Siddiqui and Rajkumar 2012, *loc. cit.*

[18] There is some debate over the methods used in these studies compared with those applied by other researchers which estimated the research and development costs, the per annum cost of capital, and the opportunity costs incurred by ten smaller companies each to bring a single cancer drug to market. DiMasi, J. A. 2018. Assessing pharmaceutical research and development costs. *JAMA Internal Medicine* 178(4): 587; Love 2017, *loc. cit.*; Prasad, V., and S. Mailankody. 2017. Research and development spending to bring a single cancer drug to market and revenues after approval. *JAMA Internal Medicine* 177(11): 1569-1575; van de Gronde, V., and T. Pieters 2018. Assessing pharmaceutical research and development costs. *JAMA Internal Medicine*. 178(4): 587-588.

[19] Siddiqui and Rajkumar 2012, *loc. cit.*

[20] DiMasi, J. A., J. M. Reichert, L. Feldman, and A. Malins. 2013. Clinical approval success rates for investigational cancer drugs. *Clinical Pharmacology and Therapeutics* 94(3): 329-235; DiMasi, J. A., H. G. Grabowski, and R. W. Hansen. 2016. Innovation in the pharmaceutical industry: New estimates of R & D costs. *Journal of Health Economics* 47(May): 20-33; Siddiqui and Rajkumar 2012, *loc. cit.*

drugs prove to be profitable.[21] Bearing fiduciary responsibilities to maximize returns on investment for their stockholders and faced with few years to recoup the costs of bringing branded drugs to market before reaching the limits of patent protection or being eclipsed by newer superior therapeutics, pharmaceutical companies seem impelled to price their products as high "as the market will bear."[22]

Because 25% of the USA national healthcare expenditures are through federal programs of which Medicare accounts for nearly two-thirds, Medicare should have immense power in the negotiation of drug prices.[23] However, the Medicare Modernization Act of 2003, which established Medicare Part D, specifically prohibits the Centers for Medicare and Medicaid Services (CMS) from negotiating directly with pharmaceutical companies to set prescription drug prices.[24, 25] Nevertheless, according to the Congressional Budget Office, lifting the ban would have little impact on lowering drug prices because prescription drug plans participating in Medicare Part D can exclude drugs from their formularies or place certain drugs in non-preferred coverage tiers that require higher co-payments by enrollees.[26] Therefore, to be competitive, Medicare-participating prescription drug plans already negotiate with pharmaceutical companies over drug prices, even though CMS itself cannot.[27]

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[21] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[22] Anderson 2014, *loc. cit.*; Bender 2018, loc. cit.; Gyawali and Sullivan 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[23] Center on Budget and Policy Priorities. 2015. *Federal Spending, Fiscal Year 2016*. Washington, DC: Center on Budget and Policies, https://www.cbpp.org/federal-spending-fiscal-year-2016 (accessed January 4, 2019); Center on Budget and Policy Priorities. 2019. *Policy Basics: Where Do Our Federal Tax Dollars Go?* Updated January 29. Washington, DC: Center on Budget and Policies. https://www.cbpp.org/research/federal-budget/policy-basics-where-do-our-federal-tax-dollars-go (accessed March 4, 2019).

[24] Brock 2010, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Lee et al. 2016, *loc. cit.*; Neumann, P. J. 2006. Emerging lessons from the drug effectiveness review project. *Health Affairs-Web Exclusive* 25(4): W262-W271. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.w262 (accessed October 8, 2019); Pearson S. D., and P. B. Bach. 2010. How Medicare could use comparative effectiveness research in deciding on new coverage and reimbursement. *Health Affairs* 29(10): 1796-1804.

[25] During 2019, bills aimed to lower the cost of drugs provided through Medicare by empowering federal negotiation of drug prices with pharmaceutical manufacturers were introduced in the USA House of Representatives and in the USA Senate H.R. 275 – Medicare Drug Price Negotiation Act. 2019. Introduced January 8. *Congress.gov*. https://www.congress.gov/bill/116th-congress/house-bill/275/text?q=%7B%22search%22%3A%5B%22S.+815%22%5D%7D (accessed January 6, 2020); S. 99 – Medicare Drug Price Negotiation Act. 2019. Introduced January 10. *Congress.gov*. https://www.congress.gov/bill/116th-congress/senate-bill/99/text (accessed January 6, 2020). On December 12, 2019, the House of Representatives passed H.R. 3, a bill that, if eventually legislated into law could create new vision, hearing and dental benefits for Medicare beneficiaries and cap their out-of-pocket drug costs, but the bill does not include provision for direct federal negotiation with pharmaceutic manufacturers on drug pricing. Stolberg, SG. 2019. House votes to give the government the power to negotiate drug prices, *The New York Times*. December 12. https://www.nytimes.com/2019/12/12/us/politics/house-prescription-drug-prices.html. (accessed January 6, 2020).

[26] Bach and Pearson 2015, *loc. cit.*; Lee et al. 2016, *loc. cit.*

[27] Lee et al. 2016, *loc. cit.*

The Affordable Care Act of 2012 gave the Department of Health and Human Services powers to waive Medicare requirements in order to test more affordable models for healthcare expenditures. Several proposals have been offered that might be effective for containing or controlling the advancing costs for the prescription delivery of anti-neoplastic chemotherapy.[28] Advocacy for strict adherence to compulsory, incentivized, or voluntary clinical management pathways, guidelines, and protocols that may lower the costs for drugs has been increasing and gaining some traction, but these methods are difficult, if even possible, to individualize and to maintain.[29] Another potential remedy is "value-based" pricing of the anti-cancer drugs provided as prescription benefits in Medicare Part B, which covers drugs administered directly by physicians and hospitals.[30] If this model were adopted by federal programs and other third-party payers, drugs could be specifically prescribed and allocated by the manufacturer at prices intended to "match the benefits" they deliver.[31]

Quantitative and Qualitative Values

Most of the linear models proposed for value-based costing of anti-cancer drugs employ two measurable variables for determining their "net-health-benefit" (NHB): 1) a fixed price in dollars for the drug, and 2) objective end results, such as overall survival time, progression-free survival time, and/or tumor response rate (partial or complete) and the associated toxicities.[32] The monetary costs of anti-cancer drug regimens then can be used to calculate the NHB in terms of dollars per month of life gained, and/or the NHB as dollars per month of progression-free survival and/or response rate. Toxicities can be inserted into the equations as negative factors. These "values" then may be compared in terms of dollars per month with the NHB of alternative drugs and other management and treatment strategies.[33] The results of randomized prospective trials with pre-established measurable therapeutic endpoint(s)—that is, overall survival, progression-free survival, response rates—have been given preference to supply data for these models, just as they have in FDA decisions to approve most anti-cancer drugs.[34]

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[28] Bach 2009, *loc. cit.*; Bach 2014b, *loc. cit.*; Bach 2015, *loc. cit.*; Bach and Pearson 2015, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*; Young 2015, *loc. cit.*; Wong, W. 2019. Where we are with value assessment in oncology. *Journal of Clinical Pathways*. 5(6): 7.

[29] Butcher, L. 2010. First published cost-effectiveness study of evidence-based clinical pathways documents 35% lower costs with no differences in survival. *Oncology Times* 32(5): 23-24 https://journals.lww.com/oncology-times/Fulltext/2010/03100/First_Published_Cost_Effectiveness_Study_of.2.aspx (accessed May 18, 2017); Dangi-Garimella. S. 2019. The value of a transparent, inclusive assessment tool in health care. *Journal of Clinical Pathways*. 5(6): 38-39; DeMartino, J. K., and J. K. Larsen. 2012. Equity in cancer care: Pathways, protocols, and guidelines. *Journal of the National Comprehensive Cancer Network* 10(Suppl 1): S1-S59; Valuck, T., and M. Castner. 2019. Incorporating patient perspectives and transparency for patient-centered value assessment. *Journal of Clinical Pathways*. 5(6): 40-41; Wong 2019, *loc. cit.*

[30] Gyawali and Sullivan 2017, *loc. cit.*; Lee et al. 2016, *loc. cit.*

[31] Bach 2014b, *loc. cit.*

[32] Bach 2015, *loc. cit.*; Bach and Pearson 2015, *loc. cit.*; Young 2015, *loc. cit.*

[33] Bach and Pearson 2015, *loc. cit.*; Young 2015, *loc. cit.*

[34] Howard et al. 2015, *loc. cit.*

Howbeit, when such measurements are lacking, FDA approval has been awarded for drugs in single-arm studies that show overwhelmingly convincing results in the treatment of certain cancers or in special situations.[35]

Evaluating the relative effectiveness of anti-cancer drugs for their contributions to overall survival, symptom-free or disease-free survival, and time to progression can be problematic. Most prospective randomized therapeutic trials do not include head-to-head comparisons of individual drugs and/or regimens, and they are very expensive to conduct.[36] Reports of benefits and toxicities from separate trials may be conflicting, and results from studies using different endpoints lead to incomparable conclusions.[37] Most importantly, survival and toxicity data derived from closely controlled prospective trials involving narrowly selected subjects do not necessarily translate into ongoing care for real-life cancer patients.[38] The American Medical Association, the American Psychiatric Association, and other professional organizations and patient advocacy groups have criticized collaborators from prestigious universities and affiliates for considering in their published reviews of drug effectiveness only the results from randomized trials to the exclusion of observational studies and other evidence.[39]

Application of quantitative models based on trials comparing drug price, survival time, response, and toxicity outcomes presents ongoing difficulties. While the relative expenses for anti-cancer drugs and drug administration derived from value-based costing models may be useful when discussing alternatives with patients before and during treatment, the inadequacies of these models must be recognized.[40] Quantitative models based on list prices for anti-cancer drugs are not stable and do not fully capture the costs of care. Over the course of the disease, inconsistencies in costs may occur if anti-cancer drugs are prescribed for adjuvant treatment or for advanced disease and whether drugs are used first-line, alone or in combination with other anti-neoplastic agents, or if they are used for rescue.[41] Inconvenience, travel, lost time, and the impact on family, friends, and community are not considered in quantitative costing models.

The major drawback to using anti-cancer drug costing in clinical care is that most monetary models are based on health benefit measures that fail to consider outcomes which patients themselves may find more beneficial than survival and relative costs; and they can introduce bias.[42] Besides effectiveness and safety in cancer care, the Institute

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[35] *Ibid*.

[36] Gyawali and Sullivan 2017, *loc. cit.*; Neumann 2006, *loc. cit*.

[37] Neumann 2006, *loc. cit*.

[38] Bender 2018, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2016, *loc. cit*.

[39] Neumann 2006, *loc. cit*.

[40] Kuznar, W. 2019. ASCO 2019 Presidential address: Removing disparities in cancer care. *Value-Based Cancer Care*. 10(4): 1, 8.

[41] Young 2015, *loc. cit*.

[42] Institute of Medicine. 2013. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: National Academies Press. https://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2013/Quality-Cancer-Care/qualitycancercare_rb.pdf (accessed October 10, 2017); Schnipper et al. 2015, *loc. cit.*; Young 2015, *loc. cit*.

of Medicine (IOM) of the National Academies of Sciences, Engineering and Medicine emphasizes the value of patient-centeredness,[43] which for the IOM means that health care should respect and be responsive to individual patient preferences, needs, and values, and "ensure that patient values guide all clinical decisions."[44]

When making decisions about treatment alternatives or choosing to forego treatment, individual patients may weigh values quite differently. For some, overall survival time may take precedence; others will prefer longer symptom-free intervals; while still others may accept less efficacious chemotherapy with the anticipation of having fewer noxious side-effects. Age, out-of-pocket expenses, pending events and opportunities, family and societal burdens, disabilities, and religious beliefs will be factored differently and may be prioritized differently by various cancer patients.[45] Experiences, attitudes, and priorities may evolve and change over the course of disease and treatment. Value factors are weighed in real-time by individual patients considering present or possible future circumstances.[46] Changing values, personal or social circumstances, financial resources, intolerance of toxicities, or inconvenience may affect certain patients' assessments of the benefits they seek from treatment and how those benefits are weighted in their on-going decisions.

Essential for any attempt to relate the costs for drugs and clinical management to benefits is the determination of which benefits are to be measured, if they can be measured, for whom are they beneficial, and only then, what are the values of the benefits.

In their commitment to patient-focused care, the American Society of Clinical Oncology (ASCO) Task Force on Cancer Care recommended simply providing patients with the health benefits of proposed treatment regimens calculated with assigned value points for survival and/or response rates gained from the results of prospective trials.[47] Positive or negative values are added for toxicity depending on how much better or worse proposed treatments were tolerated during trials compared to standard regimens. Bonus points can be added for palliation of symptoms and for treatment-free intervals, during which patients would not be subject to toxicities from treatment.[48] Individual patients potentially could modify the personal importance of health benefit factors and tolerable toxicities. Then the ASCO calculated net-health-benefit (NHB) for optional treatment regimens together with direct acquisition costs for anti-cancer and supportive drugs and the patient's expected co-payments associated with each option can be compared.[49]

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[43] *Ibid*.

[44] Institute of Medicine. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academies Press. https://www.ncbi.nlm.nih.gov/pubmed/25057539 (accessed January 7, 2017).

[45] Schnipper et al. 2015, *loc. cit*.

[46] *Ibid*.

[47] *Ibid*.

[48] *Ibid*.

[49] *Ibid*.

Although ASCO acknowledges that this method for calculating the NHB of optional regimens does not permit assessing the relative values of regimens that are not directly compared in clinical trials, it provides more flexibility than basing the value of alternative treatments on survival and toxicity alone and allows patients to interpret costs in the context of an empirically-based NHB offered by each treatment option.[50] This information, presented as bar graphs depicting clinical benefits, toxicity, and NHB with associated expected direct out-of-pocket patient costs in monetary terms per month of treatment, should be important to cancer patients when making treatment decisions, particularly those involving expensive anti-cancer drugs. The ASCO method assigns relative categorical scores "reflecting the view of the Task Force" of factors which "represent the most important component of the value assessment." However, this method does not account for "all dimensions of cost" that are important to patients, such as other medical-dental and homecare expenses, progressively increasing healthcare costs, travel and childcare costs, opportunity costs for lost work, travel and treatment time, or costs for treatment-related cosmetics and clothing, etc.[51]

To assess and compare the value of healthcare interventions and medical treatments for their presumed effects on overall years of survival and the "quality-of-life" lived during those years, economists have designed methods to measure interventions and treatments in terms of quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs).[52] These methods assign coefficients, based on averages or ranges around average weights, to variables, *judged by the investigators* to be important quality-of-life "values" derived for symptoms, complexes, and physical and/or psychological and social limitations in specific populations or test groups.[53] Generally, methods that include quality-of-life factors in their derivation of quantified outcomes or probabilities have been used in research to build health decision models and to evaluate the effectiveness of health promotion and disease prevention programs.[54]

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[50] *Ibid*.

[51] Gyawali and Sullivan 2017, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[52] Kaplan, R. M., and J. P. Anderson. 1988. A general health policy model: Update and applications. *Health Services Research* 23(2): 203-235; Sassi, F. 2006. Calculating QALYs, comparing QALY and DALY calculations. *HealthPolicy Plan* 21(5): 402-408; Schnipper et al. 2015, *loc. cit*.; Seabury, S. A., D. P. Goldman, J. R. Maclean, J. R. Penrod, and D. N. Lakdawalla. 2012. Patients value metastatic cancer therapy more highly than is typically shown. *Health Affairs* 31(4): 691-699.

[53] Kaplan and Anderson 1988, *loc. cit*.; Sassi 2006, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.; Seabury et al. 2012, *loc. cit*.

[54] Billingham I. J., K. R. Abrams, and D. R. Jones. 1999. Methods for the analysis of quality of life and survival data in health technology assessment. *Health Technology Assessment* 3(10): 1-152; EuroQol Group. 1990. EuroQol – A new facility for the measurement of health-related quality of life. *Health Policy* 16(3): 199-208; Kaplan and Anderson 1988, *loc. cit*.; Mortimer, D., and L. Segal. 2007. Comparing the incomparable? A systematic review of competing techniques for converting descriptive measures of health status in QALY-weights. *Medical Decision Making* 28(1): 66-89; Prieto, L. and J. A. Sacristán. 2003. Problems and solutions in calculating quality-adjusted life years (QALYs). *Health and Quality Outcomes* 1(80): 1-8; Richardson, G., and A. Manca. 2004. Calculation of quality adjusted life years in the published literature: A review of methodology and transparency. *Health Economics* 13(2): 1203-1210; Rubin 2016, *loc. cit*.

Outcomes in terms of QALYs or well-years of life per resource utilized have been employed by other countries for analyses of public health interventions, alternative treatments, and decisions regarding which drugs are to be included in approved formularies for care through national health systems.[57] Considering the difficulties created by various personal preferences and the complexities of obtaining sound data diversely supplied from medical records, clinical trials, and patient surveys, and then assigning arbitrary scores to selected variables, the clinical application of results from quantified costing models for quality-of-life in real individual cases would be presumptuous.[58]

At present, these methods cannot be used to price anti-cancer drugs in USA government programs, because the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Affordable Care Act of 2012 both specifically prohibit using cost-effectiveness analysis to determine coverage for prescription drugs.[59] So far, there has been social and political consensus in the USA that consideration of cost ought not to be a factor in judging alternative treatment strategies.[60] Any suggestion of adapting metric models with quality-of-life outcomes to measure "cost-effectiveness" for individual decisions regarding treatment alternatives and selection of anti-cancer drugs raises concerns about limiting patient choice and healthcare rationing.[61] Significant changes in public attitude in the USA would be needed before government policy changes are made to require cost-benefit analysis to justify payment for medical management and anti-cancer drugs and drug regimens.[62]

Personal and Public Perceptions

A review of international studies published in English on patient, public, and payer preferences for funding new anti-cancer drugs found that patients prefer medications that provide demonstrated clinical efficacy and prolonged survival, prevention, or relief of symptoms, quality-of-life benefits, and the "value of hope."[63] Cancer

[55] Bender 2018, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Young 2015, *loc. cit.*

[56] Kaplan and Anderson 1988, *loc. cit.*

[57] Erickson, P., R. Wilson, and L. Shannon. 1995. Years of healthy life. *Healthy People 2000 Statistical Notes*, no. 7. April. U.S. Department of Health and Human Services, Public Health Service Centers for Disease Control. https://www.cdc.gov/nchs/data/statnt/statnt07.pdf (accessed May 18, 2017); Kaplan and Anderson 1988, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[58] Bender 2018, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Mortimer and Segal. 2007, *loc. cit.*; Prieto and Sacristán. 2003, *loc. cit.*; Richardson and Manca. 2004, *loc. cit.*; Rubin 2016, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[59] Brock 2010, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Neumann 2006, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*

[60] Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Neumann 2006, *loc. cit.*; Pfister 2013, *loc. cit.*

[61] Gyawali and Sullivan 2017, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[62] Brock 2010, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*

[63] MacLeod, T. E., A. H. Harris, and A. Mahal. 2016. Stated and revealed preferences for funding new high-cost cancer drugs: A critical review of the evidence from patients, the public and payers. *Patient* 9(3): 201-222.

patients gave very high priority to government funding for costly anti-cancer drugs and held that expense should not be a factor for access to potentially life-extending drugs. Once treatment has commenced, patients considered funding for anti-cancer drugs as a "basic right," equated with "right to life," and withdrawal of funds for new anti-cancer drugs was viewed as unethical, even in the absence of proven effectiveness.[64] Public preferences for therapeutic efficacy and improved quality-of-life coincide with patients' preferences, emphasizing equitable access and favoring government funding for the treatment of those with high risk and vulnerability and the use of government funding for anti-cancer drugs when there are no other options.[65] Unlike patients, who are more individually focused, the public also supports funding for anti-cancer drugs that offer "significant innovations" and "wider social benefits."[66] Payers cited mainly from the United Kingdom, Canada and Australia, likewise shared preferences for funding life-saving treatments and patient-relevant health benefits with a concern for fairness.[67]

In this review, tension was noted between patients and public on one hand and payers on the other over priorities given to criteria for the allocation of resources to fund high-cost anti-cancer drugs.[68] Cancer patients, faced with life-threatening illness, consider themselves deserving of access to publicly funded health care for *any* recommended anti-cancer treatment, regardless of opportunity costs, allocation of resources, or chances for survival.[69] While most of the payers' criteria involve economic evidence and efficiency factors and maximizing public health, there was no evidence that payers share patients' and the public's preferences for autonomy in decision making and the value of hope.[70]

Whatever may be their odds for recovery, with hopes for cure and intent to prolong their own lives, cancer patients on government programs have little incentive to consider the limitations of public resources, and patients who hold generous health insurance plans with already maxed-out deductibles may demand "unproven" anti-cancer drugs regardless of savings and the costs to other stakeholders.[71] At the same time, though they may be equally desirous and realistic or unrealistic about their chances for survival and perhaps a cure, cancer patients with less generous financial backing can be faced with personal financial ruin if they choose to pursue treatment with highly expensive anti-cancer drugs.[72]

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[64] *Ibid*.

[65] *Ibid.*

[66] *Ibid.*

[67] *Ibid.*

[68] *Ibid.*

[69] *Ibid.*

[70] *Ibid.*

[71] Brock 2010, *loc. cit*.; Hall 2013, *loc. cit*.; Howard et al. 2015, *loc. cit*.; MacLeod et al., *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[72] Bach 2009, *loc. cit*.; Hall 2013, *loc. cit*.; Lakdawalla et al. 2012, *loc. cit*; MacLeod et al., *loc. cit*.; Mileshkin, L., P. E. Schofield, M. Jefford, E. Agalianos, M. Levine, A. Herschtal, J. Savulescu, J. A. Thomson, and J. R. Zalcberg. 2009. To tell or not to tell: The community wants to know about expensive

A common economic approach for assessing the "value" of goods and/or services is to determine how much the average rational consumer is willing to pay in a free market with multiple options.[73] This is an extremely difficult task, presenting many limitations when applied, even theoretically, to options for cancer care. For instance, actual out-of-pocket costs will vary depending on whether patients are able to avail themselves of government assistance programs, the terms of individual or group insurance plans, the intervals over which maximum co-payments are met, and for uninsured persons with uncertain or fluctuating incomes and those with various levels of personal or other available savings and wealth. Also problematic, the choice of options in the market for cancer care usually is quite limited.

In efforts to gain insights into patients' choices and their evaluations of treatment with expensive new anti-cancer drugs, investigations have been undertaken attempting to test the willingness of patients to pay. A population survey in Australia found that 51% of all respondents said they were willing to pay for an expensive anti-cancer drug that could prolong survival 4-6 months more than the mean two years overall survival expected with standard regimens; 71% were willing to pay for drugs with less toxicity but no improved survival compared to standard chemotherapy; and 76% were willing to pay for a promising new drug with a 50% response rate when no standard treatment is available.[74] Households with higher incomes were significantly more willing to pay for expensive anti-cancer drugs in each of those situations; though a majority of all respondents believed that government should pay for the drugs, an opinion which agrees with cancer patients and the public view in international reports.[75]

A study done in the USA gave members of two separate groups of cancer patients theoretical therapeutic options designated to treat the disease with which they were afflicted.[76] One scenario offered melanoma patients the option of certain survival for 2.0 years with standard treatment or a 20% *chance* of living at least 4.5 years with a new more expensive anti-cancer drug; the other scenario offered breast cancer patients 1½ years certain survival with standard treatment or a 10% *chance* of living 4.0 years or more with an expensive multi-drug regimen.[77] While theoretical, this study incorporated real economic models and realistic survival data from anti-cancer drug-trial results for the types of cancers presented. Over three-quarters of the patients in this study preferred the *chance* for longer survival with the more costly treatment, even though the odds for years of survival were the same with standard treatment in both theoretical scenarios.[78] Most of the patients in this study, when confronted with a lethal disease and

anticancer drugs as a potential treatment option. *Journal of Clinical Oncology* 27(34): 5830-5837; Pfister 2013, *loc. cit.*; Prasad et al. 2017, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[73] Seabury et al. 2012, *loc. cit.*

[74] Mileshkin et al. 2009, *loc. cit.*

[75] MacLeod et al., *loc. cit.*; Mileshkin et al. 2009, *loc. cit.*

[76] Lakdawalla et al. 2012, *loc. cit.*

[77] *Ibid.*

[78] *Ibid.*

potentially short life-spans, chose to take their chances for longer survival with newer, more expensive treatments than the certainty of shorter survival times with standard therapy; but when asked to evaluate treatment by monetary cost, only a quarter of the subjects were willing to pay $75,000 or more for the newer treatment.[79] Cancer patients in the upper fourth income quartile were ten times more willing to pay for the new multi-drug anti-cancer treatment than patients in the lowest income quartile, and twice as willing as patients in the second income quartile.[80] Not surprisingly, cancer subjects in the study who reported the highest incomes were the most willing to pay the most.[81] It may be conjectured that patients with lower incomes, if forced by economic circumstances or when freely considering individually important benefits of treatment along with their financial burdens, might more likely tend to choose anti-cancer regimens with less promise for longer overall or progression-free survival at lower costs.[82] Notwithstanding these observations, individual cancer patients, regardless of personal income levels, could freely and reasonably choose a lower-priced drug treatment option or no anti-cancer chemotherapy at all.

Because of the dreaded natural progress that patients may associate with cancer diagnoses and the fact that most advanced cancers are incurable, many cancer victims with unrealistic expectations for recovery will choose chemotherapy in spite of possible severe toxicities and high prices for anti-cancer drugs. This has been particularly so for well-insured patients and some patients who are on government programs and thereby sheltered from large out-of-pocket costs.[83] However, health insurance premiums and deductibles have been shifting dramatically to workers during the past decade,[84] and insured patients may have direct out-of-pocket costs for cancer care approaching $5,000 a year, even after excluding indirect costs, which are greater than those of other chronic diseases.[85] Inasmuch as Medicare has no upper limit on co-payments, the out-of-pocket payments for drugs could reach $10,000 a year for beneficiaries who do not have supplemental insurance or a patient-assistance program from the manufacturer.[86]

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[79] *Ibid*.

[80] *Ibid*.

[81] *Ibid*.

[82] Mileshkin et al. 2009, *loc. cit*.; Pfister 2013, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[83] Brock 2010, *loc. cit*.; Hall 2013, *loc. cit*.; Howard et al. 2015, *loc. cit*.; Prasad et al. 2017, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[84] Brock 2010, *loc. cit*.; Szabo, L. 2017. As drug costs soar, people delay or skip cancer treatments. *Shots – Health News NPR*. March 15. https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments (January 2, 2018); Zafar 2016, *loc. cit*.

[85] Siddiqui and Rajkumar 2012, *loc. cit*.; Zafar 2016, *loc. cit*.; Zafar, S. Y., J. M. Peppercorn, D. Schrag, D. H. Taylor, A. M. Goetzinger, X. Zhong, and A. P. Abernethy. 2013. The toxicity of cancer treatment: A pilot study assessing out-of-pocket expenses and the insured cancer patient's experience. *The Oncologist*. 18: 381-390.

[86] Szabo 2017, *loc. cit*.

For anti-cancer drugs that cost $120,000 per year, the out-of-pocket expenses could be as high as $30,000.[87]

Insured patients with high co-payments for prescription drugs and Medicare patients without co-insurance may find that potentially efficacious but highly expensive anti-cancer drugs are beyond their financial reach.[88] Fifty per cent of Medicare cancer patients are spending more than 10% of their incomes on out-of-pocket costs for treatment, and 13% of non-elderly cancer patients spend at least 20% of their incomes for their cancer care.[89] A national survey found that since the Affordable Care Act went into effect many households still lack resources to cover the standard cost-sharing required by insurance plans available on exchanges created by the Affordable Care Act.[90] Only 53% of households had sufficient funds to pay a medium, mid-range, yearly deductible of $2,400; and only 45% could pay a median high-range deductible of $5,000.[91] High out-of-pocket costs are associated with greater odds of noncompliance, which is a waste of resources, whether private or public, and results in poorer individual outcomes.[92]

The current population of 40 million persons over age 65 years in the USA is expected to increase to more than 70 million during the next two decades. Growth in this population, when the prevalence of many cancers has been the highest, is expected to substantially increase the national expenditures for cancer care of older citizens.[93] Insurance providers to some extent might build in prepaid costs for plans that would cover expensive anti-cancer drugs promising possibilities for longer survivals compared to lower-cost standard therapy, though with the economic certainty of price elasticity of demand for those policies.[94] But government payers must consider both individual and community healthcare needs as well as financial constraints and political concerns when funding decisions are made regarding treatment alternatives, matters which are of little concern to cancer patients who deem government funding for anti-cancer drugs as a "basic right" or a public which thus far favors funding for anti-cancer drugs, independent of patients' abilities to pay.[95]

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[87] Tefferi, A., H. Kantarjian, S. V. Rajkumar, L. H. Baker, J. L. Abkowitz, J. W., J. W. Adamson, et al. 2015. In support of a patient driven initiative and petition to lower the price of cancer drugs. *Mayo Clinic Proceedings* 90(8): 996-1000.

[88] Brock 2010, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[89] Zafar 2016, *loc. cit.*

[90] *Ibid.*

[91] *Ibid.*

[92] Prasad et al. 2017, *loc. cit.*; Ramsey, S. D., A. Bamsal, C. R. Fedorenko, D. K. Blough, K. A. Overstreet, V. Shankaran, and P. Newcomb. 2016. Financial insolvency as a risk factor for early mortality among patients with cancer. *Journal of Clinical Oncology* 34(9): 980-986; Szabo 2017, *loc. cit.*; Tefferi et al. 2015, *loc. cit.*; Zafar 2016, *loc. cit.*; Zafar et al. 2013, *loc. cit.*

[93] Mariotto et al. 2011, *loc. cit.*; National Cancer Institute 2018, *loc. cit.*

[94] Lakdawalla et al. 2012, *loc. cit*; Seabury et al. 2012, *loc. cit.*

[95] Gyawali and Sullivan 2017, *loc. cit.*; MacLeod et al., *loc. cit.*

With a growing world population and increasing life expectancy and economic disparities at home and abroad, Americans are confronted with challenging individual and societal decisions concerning the relative values of health care.[96] Addressing the steeply rising prices for anti-cancer drugs, there are growing voices from the medical profession for the costs of cancer chemotherapy to be related to the values they deliver.[97] And a recent USA government request from CMS for comments on a proposed International Pricing Index Model for Medicare Part B Drugs to become regionally effective in 2020, also included the consideration of value-based payment arrangements based on "indications" or outcomes.[98]

While there is growing public apprehension and increasing political attention regarding the economic implications of escalating costs for cancer care and prices for anti-cancer drugs over the past decade, the proposed econometric costing models, just reviewed, do not satisfactorily relate to the personal and societal values which patients and the public so far express and may individually prefer. Formulae that factor survival, disease- or disability-free status, and toxicities to evaluate outcomes from treatment with anti-cancer drugs relative to expenses, expressed as prices *per se*, do not fully capture and measure the myriad of present and changing individual and societal values and the personal costs that are experienced. Moreover, the foregoing review exposes potential conflicts between tangible and intangible costs, qualitative and quantitative values, and

[96] Cire, B. 2016. World's older population grows dramatically. NIH-funded census bureau report offers details on global aging phenomenon. *News Room*. March 28. National Institute of Aging. National Institutes of Health, Department of Health and Human Services. https://www.nia.nih.gov/newsroom/2016/03/worlds-older-population-grows-dramatically (accessed April 27, 2017); He, W., D. Goodkind, and P. Kowal. 2016. *An Aging World: 2015*. U.S. Census Bureau, International Population Reports, P95/16-1. Washington, DC: U.S. Government Publishing Office. https://www.census.gov/content/dam/Census/library/publications/2016/demo/p95-16-1.pdf (accessed April 27, 2017); Institute for Policy Studies. 2017. Income inequality. Household and family income. *Inequality.org*. https://inequality.org/income-inequality/ (accessed April 27, 2017); Pontifical Council for Justice and Peace. 2004. *Compendium of the Social Doctrine of the Church*. no. 192. http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html (accessed February 9, 2018); Population Reference Bureau. 2016. *Human Population: Population Growth, 2016*. https://www.prb.org/Publications/Lesson-Plans/HumanPopulation/PopulationGrowth.aspx (accessed April 27, 2017); Roser, M., H. Ritchie, and E. Ortiz-Ospina. 2019. World population growth. First published 2013, most recent substantial revision in May 2019. *OurWorldinData.org*. https://ourworldindata.org/world-population-growth (accessed October 16, 2019).

[97] American Society of Clinical Oncology. 2014. Value in cancer care. *ASCO in Action*. January 21. Alexandria, VA: American Society of Clinical Oncology. https://www.asco.org/advocacy-policy/asco-in-action/asco-action-brief-value-cancer-care (accessed May 3, 2017); Bach 2015, *loc. cit.*; Bach and Pearson 2015, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Society of Gynecologic Oncology 2016, *op. cit.*; Young 2015, *loc. cit.*

[98] Centers for Medicare & Medicaid Services. 2018b. CMS-5528-ANPRM, RIN 0938-AT91 Medicare Program; International Pricing Index Model for Medicare Part B Drugs. https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF (accessed December 23, 1018).

personal and public expectations, and raises serious concerns that the effectiveness of these so-called value-based remedies would be gauged by utilitarian criteria.

Ethical Principles for Value-Based Decisions

Moral issues abound in decisions regarding the treatment of persons living in socioeconomic community when expensive anti-cancer drugs are concerned. Libertarian theorists champion principles of economic autonomy and individual freedom based on free-market-based supply-and-demand valuation and pricing for health care determined by individual choices and willingness to pay for care and medications.[99] Libertarian principles, however, could thwart communal contributions and overlook structural impediments which limit autonomy and access to health care for those who are poor or otherwise disadvantaged. Metric methods, on the other hand, such as those which calculate values of personal health care based on increases in QALYs or decreases in DALYs, elicit anthropological and normative concerns.[100] Utilization of quantitative methods intended to provide with limited resources the greatest value in health care for the greatest number of citizens could bias against elderly and/or disabled people; as older persons have fewer life-years to quantify, and disabled persons generally have shorter, more painful life-years remaining than younger, able people with whom they are compared.[101] Basing the value of cancer care and anti-cancer drugs on utilitarian calculations and confining criteria to communitarian standards diminish attention to individual persons in the society and raise concerns for justice and the needs of the most vulnerable.[102]

To counter misgivings about the use of libertarian free-market approaches and utilitarian calculations for access to health care and medications, this article advocates enlisting the ethical principles of *human dignity* and the *common good* for both personal and corporate decisions regarding cancer care and the production, distribution, and use of potentially life-prolonging, but sometimes expensive anti-cancer drugs. Human dignity and the common good are proclaimed ethical principles of Christianity and other religious faiths, evolving philosophical concepts underlying contemporary Western political traditions and laws, and affirmed by international declarations.[103] A

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[99] National Libertarian Committee. 2017. Healthcare. *Libertarian*. Alexandria, VA: National Libertarian Committee. https://www.lp.org/issues/healthcare/ (accessed April 16, 2017).

[100] Kaplan and Anderson 1988, *loc. cit.*; Prieto and Sacristán. 2003, *loc. cit.*; Rubin 2016, *loc. cit.*; Sassi 2006, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[101] Glannon, W. 2005. *Biomedical Ethics*. Oxford, UK: Oxford University Press, pp. 149-151; Harris, J. 2002. QALYfying the value of life. In *Contemporary Readings in Biomedical Ethics*. edited by W. Glannon. New York, NY: Harcourt College Publishers, pp. 428-429; John Paul II. 1981. *Laborem exercens*, no. 22. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_14091981_laborem-exercens.html (accessed April 25, 2019).

[102] Gately, P., A. Beck, and D. A. Jones. 2011. *Healthcare Allocation and Justice*: *Applying Catholic Social Teaching*. London, UK: Catholic Truth, pp. 18-27, 32-36.

[103] *Catechism of the Catholic Church*. 1993. Vatican City: Libreria Editrice Vaticana. https://www.vatican.va/archive/ENG0015/_INDEX.HTM (accessed October 10, 2017), nos. 1738, 1905-1907, 2258;

comprehensive exploration of either topic, however, is far too wide-ranging for an article of this proposed length. Because they are foundational, quite current and inclusive, Catholic ethical and social teachings on human dignity and the common good were chosen to ground this essay and offer holistic guidelines for morally good decisions when evaluating access and the costs, values, and use of cancer care and anti-cancer drugs.

The sanctity of human life is a fundamental Christian tenet based on Scripture and natural law.[104] Faith in the sanctity of human life is recognized as the immeasurable intrinsic worth of human persons, each of whom is "above all value."[105] Catholic teachings on human dignity and the common good rest upon this conviction.[106] Whether drawn from Christian tenets and/or from philosophy, in this essay *human dignity* denotes the incalculable worth of *every* human being, and the *common good* denotes the social fact that the good of each individual human person is necessarily related to the *good of others*.

Declaration of Independence of the United States, July 4, 1776. https://www.archives.gov/exhibits/charters/declaration_transcript.html (accessed, March, 2013); Goodman, M. 2005. Human dignity in Supreme Court constitutional jurisprudence. *Nebraska Law Review*. 84(3): 740-794. https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1241&context=nlr (accessed December 5, 2019); Gusgee, D. P. 2013. *The Sacredness of Human Life. Why an Ancient Biblical Vision is Key to the World's Future*. Grand Rapids, MI/Cambridge, UK: William B. Eerdmans Publishing Company. pp. 16-110, 217-257; Hussain, W. 2018. The common good. In *The Stanford Encyclopedia of Philosophy*. (Spring), edited by E. N. Zalta. https://plato.stanford.edu/archives/spr2018/entries/common-good/ (accessed December 6, 2019); *International Covenant on Economic, Social and Cultural Rights*. 1966. Adopted on 16 December through the United Nations General Assembly Resolution 2200A (XXI). https://www.refworld.org/docid/3ae6b36c0.html (accessed December 12, 2019); Locke J. 2015. Two Treatises of Government. In *Two Treatises of Government and A Letter Concerning Toleration.* Introduction by H. Morley. London, UK: Philip Mould, Ltd., Book I. §67, Book II. §5, §6, §31, §135; McCrudden C. 2008. Human dignity and judicial interpretation of human rights. *European Journal of International Law*. 19(4): 655-724. file:///C:/Users/mjc92028/Downloads/SSRN-id1162024.pdf (accessed December 5, 209); Moltmann, J. 1984. *On Human Dignity. Political Theology and Ethics*. translated by M. D. Meeks. Philadelphia, PA: Fortress Press. pp. 3-17, 19-35; Nickel, J. 2019. Human rights. In *The Stanford Encyclopedia of Philosophy*. (Summer). edited by E. H. Zalta. https://plato.stanford.edu/archives/sum2019/entries/rights-human/ (accessed December 6, 2019); Peterson, N. Human dignity, international protection. 2015. In *Oxford Public International Law*. Oxford University Press. https://opil.ouplaw.com/view/10.1093/law:epil/9780199231690/law-9780199231690-e809 (accessed 12/12/19); Piechowiak, M. 2019. *Plato's Conception of Justice and the Question of Human Dignity*. Berlin, DE: Peter Lang GmbH, Internationaler Verlag der Wissenschaften. pp. 17-18, 26-27, 41-43, 153-157; Rao, N. 2013. Three concepts of dignity in constitutional law. *Notre Dame Law Review*. 86(1): 183-271. https://scholarship.law.nd.edu/ndlr/vol86/iss1/4 (accessed December 4, 2019); Soulen, R. K., and L. Woodhead. 2006. Contextualizing human dignity. In *God and Human Dignity*. edited by S. R. Kendall, and L. Woodhead. Grand Rapids, MI/Cambridge, UK: William B. Eerdmans Publishing Company, 2006. pp.1-12; *Universal Declaration of Human Rights*. 1948. Adopted and proclaimed by the United Nations General Assembly on 10 December, Resolution 217 A. https://www.jus.uio.no/lm/un.universal.declaration.of.human.rights.1948/portrait.a4.pdf (accessed December 12, 2019).

[104] Gusgee 2013. *op. cit*., pp. 16-110, 216-242.

[105] Kant I. 2019. *Groundwork of the Metaphysics of Morals*. translated by T. K. Abbott. Monee, IL: Compass Circle, pp. 56-58.

Personhood and Human Dignity

The dignity of human persons is the foundation of a moral society.[107, 108] Drawing on principles expounded by Karol Wojtyla in 1960 before he became Pope John Paul II in 1978.[109] it here is asserted that moral agents, intent on virtue, should employ personalistic norms when discerning the goodness and potential outcomes of their decisions.[110] Certain fundamental aspects of human personhood are especially relevant for the examination of value-based costing for anti-cancer drugs and cancer care. First, the human person is a free and inviolable *subject* and must never be treated as an object or a means to an end.[111] Every human subject is at least potentially a rational, knowing, judging, and freely deciding being.[112] This dimension of the human person insists on individual freedom to choose among moral options, including options for cancer care.[113] Second, the human person is essentially *corporeal*, that is, embodied.[114] All considerations of cancer care are related to embodied life. But to focus on the body apart from the broader relational, psychological, emotional, and spiritual dimensions of personhood when deliberating the benefits of treatment is a reductionist consideration of human dignity and worth.[115] The reality of human embodiment should not diminish these other essential human attributes when medical care and cost decisions are made. Third, the human person is in *relationship* to self, neighbor, social groups, and the

[106] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2258.

[107] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1700; United States Conference of Catholic Bishops. 1986. *Economic Justice for All: Pastoral Letter on Catholic Social Teaching and the U.S. Economy*. nos. 13-15. https://www.usccb.org/upload/economic_justice_for_all.pdf (accessed July 22, 2019); United States Conference of Catholic Bishops. 2019. *Life and Dignity of the Human Person*. https://www.usccb.org/beliefs-and-teachings/what-we-believe/catholic-social-teaching/life-and-dignity-of-the-human-person.cfm (accessed April 15, 2019).

[108] The Preamble of the United Nations Universal Declaration of Human Rights 1948. *op. cit.*, recognized that "inherent dignity" and the "equal and inalienable rights of all members of the human family" are the "foundation of freedom, justice and peace in the world."

[109] Wojtyla, K. 1981. *Love and Responsibility*. New York, NY: Farrar, Straus and Giroux, Inc., pp. 22-27, 31, 40-43.

[110] Vatican Council II 1965. *Gaudium et spes. Pastoral Constitution of the Church in the Modern World.* nos. 16, 35.

[111] Wojtyla 1981. *op. cit.*, pp. 22-27, 41.

[112] Wojtyla 1981. *op. cit.*, pp. 22, 24, 27.

[113] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1730-1738, 1749-1761, 1777, 1782, 1783; John Paul II, 1993. *Veritatis splendor*. nos. 52, 54, 62-64, 84, 110. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_06081993_veritatis-splendor.html (accessed November 9, 2018).

[114] Wojtyla 1981. *op. cit.*, pp. 22-24, 54-55, 121.

[115] John Paul II 1993. *op. cit.*, nos. 48-50; Vatican Council II 1965. *op. cit.*, no. 14; Wojtyla 1981. *op. cit.*, pp. 54-55, 121.

material world.[116] Fourth, because human life is sacred and each human being is a unique subject, all persons share *equally* in human dignity.[117]

Community and the Common Good

Given the social nature of human beings, individual persons ideally must relate to a common good.[118] The human person is fully realized by living and working in community with others.[119] Within their levels of competence, therefore, both as individuals and as groups, members of human society are obliged to contribute to the common welfare in harmony with the needs of the community and the norms of justice.[120] The common good, consequently, entails both rights and duties within the moral order.[121] An ethical approach based on human dignity and the common good aspires to assure that every person rightfully shares in the benefits and the cares of the community.[122] The common good embraces the sum of those social conditions which favor human fulfillment for all members of the society (persons, families, and groups).[123] Catholic teachings insist on the fundamental right of each human being to bodily integrity, including proper food, clothing, shelter, rest, adequate health care, and necessary social services.[124] The common good is fully realized when economic, political, and social conditions ensure protection for the fundamental rights of *all* individuals, enabling them to reach their common goals and common purpose.[125] The common good, there-

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[116] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1738, 1905-1907; Wojtyla 1981. *op. cit.*, pp. 24, 28-29, 31, 40-42.

[117] Benedict XVI. 2005. *Deus caritas est*. nos. 1, 16, 19. http://w2.vatican.va/content/benedict-xvi/en/encyclicals/documents/hf_ben-xvi_enc_20051225_deus-caritas-est.html (accessed April 4, 2018); Benedict XVI. 2009. *Caritas in veritate*. nos. 11, 19, 21. http://w2.vatican.va/content/benedict-xvi/en/encyclicals/documents/hf_ben-xvi_enc_20090629_caritas-in-veritate.html (accessed July 21, 2019); *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1738; nos. 1700, 1738; Vatican Council II 1965. *op. cit.*, nos. 27, 29, 60, 66, 73; Wojtyla 1981. *op. cit.*, pp. 27, 41, 250.

[118] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1738, 1905-1907; John XXIII. 1961. *Mater et magistra.* nos. 219, 220. http://w2.vatican.va/content/john-xxiii/en/encyclicals/documents/hf_j-xxiii_enc_15051961_mater.html (accessed April 4, 2018); Vatican Council II 1965. *op. cit.*, nos. 25-27,30, 32, 63.

[119] United States Conference of Catholic Bishops 1986. *op. cit.,* no. 15. Vatican Council II 1965. *op. cit.*, nos. 16, 35.

[120] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2239; John XXIII. 1963. *Pacem in terris*. nos. 31-33, 48, 53. http://w2.vatican.va/content/johnxxiii/en/encyclicals/documents/hf_jxxiii_enc_11041963_pacem.html (accessed April 4, 2018); Pius XI, Pope. 1931. *Quadragesimo anno*. no. 85. http://w2.vatican.va/content/pius-xi/en/encyclicals/documents/hf_p-xi_enc_19310515_quadragesimo-anno.html (accessed May 10, 2019); Vatican Council II 1965. *op. cit.*, nos. 30, 65, 69, 73, 75; Wojtyla 1981. *op. cit.*, pp. 29-31.

[121] John XXIII 1961. *op.* cit., nos. 66, 67, 147; Vatican Council II 1965. *op. cit.*, nos. 26,30, 56, 60, 65, 69, 73-75.

[122] Pontifical Council for Justice and Peace 2004. *op. cit.*, nos. 171-175, 185.

[123] John XXIII 1961 *op.* cit., nos. 65, 74, 219; Vatican Council II 1965. *op. cit.*, nos. 26, 60, 73, 74.

[124] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2288; John XXIII 1963. *op. cit.*, no. 11.

[125] John XXIII 1961. *op. cit.*, no. 65; John XXIII 1963. *op. cit.*, nos. 60, 62; John Paul II. 1991. *Centestimus annus*. no. 10. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_

fore, demands that special consideration must be given to those persons who are in any way the weaker members of society.[126]

Rights and Responsibilities

Thus, moral decisions are made by human subjects living together in the material world. During the twentieth century, evolution of the science and philosophy of bioethics "gravitated to an ethics of autonomy," which upheld *personal choice* as the "highest moral value."[127] But an ethic that champions only the liberty to make individual decisions, aside from context, does not fully address the intrinsic *morality* of an act and its conformity with the fundamental aspects of *personhood*.[128] While "just freedom of action" by individual citizens is a condition of the common good, this should never wrong any persons or groups within the community.[129]

According with the asserted personalistic norms to discern fully the goodness of decisions, moral agents absolutely must take account of the dimension of relationship.[130] When tasked with health care decisions, the potential outcomes for both personhood and the public interest should always be considered.[131] Decisions regarding the availability, costs, and use of expensive anti-cancer drugs by their very nature involve not only individual patients, their families and care-givers, but also social groups with whom patients are related, and ultimately the extended economic community and political structure.[132] Therefore, an individual's personal decisions regarding cancer care and the use of anti-cancer drugs should be made in the context of living with other human beings; and producers and policy-makers, responsible for the provision and distribution of health care assets, must honestly assess, as best they can, the effects their decisions may have for all stakeholders.[133]

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jp-ii_enc_01051991_centesimus-annus.html (accessed April 5, 2018); Pontifical Council for Justice and Peace 2004. *op. cit.*, no. 164.

[126] Gately et al. 2011. *op. cit.*, pp. 32-36; John XXIII 1961. *op. cit.*, no. 20; Pontifical Council for Justice and Peace 2004. *op. cit.*, no. 182; United States Conference of Catholic Bishops 1986. *op. cit.*, no. 16; United States Conference of Catholic Bishops 2019. *Seven Themes of Catholic Social Teaching*. https://www.usccb.org/beliefs-and-teachings/what-we-believe/catholic-social-teaching/seven-themes-of-catholic-social-teaching.cfm. (accessed April 15, 2019).

[127] Callahan, D. 1994. Bioethics: Private choice and common good. *Hastings Center Report* 24(3): 28-31.

[128] Callahan 1994, *loc. cit.*; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1738; 1950-1959; Wojtyla 1981. *op. cit.*, pp. 22-28, 54-55, 250.

[129] Pius XI 1931. *op. cit.*, nos. 25, 57, 58; Vatican Council II 1965. *op. cit.*, nos. 29, 59, 60, 66.

[130] Vatican Council II 1965. *op. cit.*, nos. 16, 35; Wojtyla 1981. *op. cit.*, pp. 24, 28-29 31, 40-43.

[131] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1738; United States Conference of Catholic Bishops 1986. *op. cit.*, nos. 1, 2, 6, 13.

[132] Pius XI 1931. *op. cit.*, nos. 25, 57, 58; Vatican Council II 1965. *op. cit.*, no. 31.

[133] Callahan 1994, *loc. cit.*; Pius XI 1931. *op. cit.*, nos. 25, 57, 58.

Justice and Charity

Morally good decisions and acts all should intend justice and embrace charity for oneself and for one's neighbor.[134] Individual decisions concerning the clinical management of cancer, which may or may not involve expensive travel, facilities, other pharmaceuticals, discomforts, untoward effects, and so forth, normally will be considered in relation to possible or likely short or long-term disease-free remission, hope, personal productivity, and whatever else may be important to a particular patient. Patients, family, and members at all levels of the community should be guided by commitments to justice and benevolence when making decisions concerning cancer care, costs, and the allocation of relevant resources.[135] Justice conforms to the Truth.[136] Justice pursues virtue: that which is right and good.[137] Justice is impartial and fair.[138] Perfect justice and truth are in conformation with Love.[139] To meet the moral demands of making medical and health care decisions which respect human dignity and promote the common good, justice in our human society must be tempered with neighborly love.[140] Love is not self-centered. Love is self-giving.[141]

Cancer patients and their supporters committed by good wills to justice and neighborly love should carefully reflect on the results which care and treatment decisions may have for other patients and the community at large.[142] Because love is self-giving,[143] this moral responsibility could ethically require patients to forego certain

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[134] Benedict XVI 2005. *op. cit.*, nos. 1, 16-22, 26, 28b, 30, 31; John Paul II 1993. *op. cit.*, nos. 64, 85. Vatican Council II 1965. *op. cit.*, nos. 16, 21, 26, 30, 72, 76, 93; Wojtyla 1981. *op. cit.*, pp. 41-43.

[135] Benedict XVI 2005. *op. cit.*, nos. 1, 16, 18-20, 22, 28-31, 39; Vatican Council II 1965. *op. cit.*, nos. 21, 26, 69, 72, 73, 76, 90, 93.

[136] Aquinas, T. 2017. In *The Summa Theologica of St. Thomas Aquinas*. 2nd revised edition. Literally translated by Fathers of the English Dominican Province, 1920. I, q. 21, a. 2. New Advent Online Edition. http://www.newadvent.org/summa. (accessed April 10, 2019); John XXIII 1961. *op. cit.*, no. 215; John Paul II. 1987. *Solicitudo rei socialis.* no. 33. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_30121987_sollicitudo-rei-socialis.html (accessed April 2, 2019)

[137] Aquinas 2017. *op. cit.*, I–II, q. 94, a. 2.

[138] Benedict XVI 2005. *op. cit.*, no. 26; John Paul II 1991. *op. cit.*, nos. 10, 11, 34, 47; Leo XIII. 1891. *Rerum novarum*. nos. 33, 34, 36, 38. http://w2.vatican.va/content/leo-xiii/en/encyclicals/documents/hf_l-xiii_enc_15051891_rerum-novarum.html (accessed January 13, 2020); Pius XI 1931. *op. cit.*, nos. 57, 58; Vatican Council II 1965. *op. cit.*, nos. 63, 66.

[139] Aquinas 2017. *op. cit.*, I. q. 21, a. 2; John Paul II. 1988. *Christifedeles laicia.* http://w2.vatican.va/content/john-paul-ii/en/apost_exhortations/documents/hf_jp-ii_exh_30121988_christifideles-laici.html (accessed April 6, 2018); Wojtyla 1981. *op. cit.*, pp. 42-43, 250.

[140] Benedict XVI 2005. *op. cit.*, nos. 1, 18-20, 28b, 30, 31, 39; John XXIII 1961. *op. cit.*, no. 215; John Paul II 1987. *op. cit.*, *nos*. 33, 47; John Paul II 1991. *op. cit.*, no. 58; Leo XIII 1891. *op. cit.*, no. 22; Vatican Council II 1965. *op. cit.*, nos. 21, 93; Wojtyla 1981. *op. cit.*, p. 42.

[141] Benedict XVI 2005. *op. cit.*, nos. 30, 33, 34; John Paul II 1987, *op. cit.*, no. 40; John Paul II 1993. *op. cit.*, nos. 17, 94, 107; Wojtyla 1981. *op. cit.*, pp. 29-30, 125-126.

[142] Benedict XVI 2005. *op. cit.*, nos. 28-30; John Paul II 1987, *op. cit.*, nos. 28, 33, 42, 49.

[143] Benedict XVI 2005. *op. cit.*, nos. 30, 33, 42, 49; John Paul II 1993. *op. cit.*, nos. 17, 107.

treatments that are likely to be futile and assign available resources, especially scarce resources, to another person or persons for whom they are expected to be more effective.[144] Political, corporate, and group officials and leaders surely must recognize that their determinations regarding production and distribution and access to resources for health care may even affect individuals and human interests laying beyond their immediate constituencies. Promoting justice and loving concern for the weak and the poor should guide policy-makers and managers deliberating these questions toward ethically well-intentioned unselfish decisions grounded in the principles of human dignity and the common good.[145]

Because cancer can be a terminal illness when the diagnosis is made at an advanced stage or the disease is rapidly progressing after treatment failures and the prognosis is poor for reversing or slowing the course, decisions concerning prolongation of life may be encountered.

Prolongation of Life in Terminal Illness

Death is an inevitable reality for all corporeal human subjects. The reality of eventual death, therefore, is pertinent to every consideration for care and evaluation of treatment options by subjects with terminal illnesses, particularly those cancer patients who face decisions involving the use of expensive anti-cancer drugs with little likelihood of significantly extending their lives. For the community, decisions regarding the value of using costly pharmaceuticals in such situations are just as arduous.

It is natural for human beings to desire prolongation of their lives. No matter how helpless, no matter how feeble, human life is a good to be maintained. The questions then are: to what extent, in what situations, and at what costs? Overall, the prognosis for longer survival following a diagnosis of cancer has increased dramatically through the past fifty years, and advances in the medical sciences give increasing hope to current cancer patients.[146] Even with a diagnosis of terminal illness, prognosis can be improved and life extended in many cases. As treatments become standard in the best practice of medicine, maintaining one's own health while living in unity with family and supporting the common good becomes an ordinary expectation for many cancer pa-

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[144] Benedict XVI 2005. *op. cit.*, nos. 30, 33, 34; John Paul II 1987, *op. cit.*, no. 40; John Paul II 1993. *op. cit.*, nos. 17, 64, 85, 94, 107; Vatican II 1965. *op. cit.*, nos. 21, 72, 73, 90.

[145] Benedict XVI 2005. *op. cit.*, nos. 26, 28a, 29, 30; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1750-1761; John XXIII 1961. *op. cit.*, nos. 37, 39, 40, 96; John XXIII 1963. *op. cit.*, nos. 9, 28, 31-33, 60, 62, 77; John Paul II 1987, *op. cit.*, nos. 26, 28, 33, 36, 39, 42, 47; John Paul II 1991. *op. cit.*, nos. 11, 47, 58; John Paul II. 1995. *Evangelium vitae.* nos. 59, 87, 90. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html (accessed April 29, 2019); Leo XIII 1891. *op. cit.*, 32; Vatican Council 1965. *op. cit.*, nos. 21, 69, 72, 73, 74, 90.

[146] National Institutes of Health. 2010. *NIH fact sheets*: *Yesterday, today & tomorrow. Cancer*. Updated October, 2010. Washington, DC: U.S. Department of Health and Human Services. https://report.nih.gov/nihfactsheets/Pdfs/Cancer(NCI).pdf (accessed May 22, 2017); Weaver, M. 2010. Cancer survival rates have doubled since 1970s, research shows. *The Guardian*. July 12. https://www.theguardian.com/science/2010/jul/12/cancer-survival-rates-doubled (accessed April 25, 2017).

tients, so long as they are able to sustain the effects of therapy. The common duty of healthy stewardship over one's own life demands ordinary care, nutrition, fluids, and fitness to the extent possible.[147, 148] It does not oblige a terminally ill patient to undergo any medical treatment that may prolong his or her life beyond its natural course, except perhaps in a situation whereby surrendering life without a struggle would adversely affect others and/or the common good.[149] Decisions whether or not to pursue medical treatment should reside with the free, competent patient, the one charged with first responsibility for the care of his or her own personal life and faculties.[150] Neither the physician nor the community, but only the free subject-patient can validly judge the personal value of his or her own cancer care.[151] It is the responsibility of the physician to honestly counsel the patient on expected outcomes with various courses of management and therapy, and it is the obligation of the community to assure equitable distribution of resources for standard care,[152] but it is the responsibility of the free patient to make the final decision about his or her care.[153]

There is little debate among qualified oncologists over the efficacy of standard chemotherapy and protocols used for first-line management of the majority of common cancers, generally with generic anti-cancer drugs.[154] At costs of tens or even hundreds of thousands of dollars, however, the addition of some newer anti-cancer drugs to first-line chemotherapy regimens or for treatment of progressive disease may add statistically significant but too often practically disappointing increases in survival.[155] Nonetheless, demonstrations of intra-tumoral and both intra- and inter-metastatic genomic heterogeneity of some human cancers and their treatment hold promise for improved prognosis with treatment using multiple anti-cancer drugs, including regimens with new agents.[156]

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[147] United States Conference of Catholic Bishops. 2018. *Ethical and Religious Directives*, 6th ed. no. 58. https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf. (accessed October 1, 2019).

[148] There is a long and continuing debate over what constitutes *ordinary care*, but that discussion lies outside the scope of this essay. (Ashley, B. M., and K. D. O'Rourke. 1997. *Health Care Ethics: A Theological Analysis.* Washington, DC: Georgetown University Press. pp. 420-428; O'Donnell, T. J. 1991. *Medicine and Christian Morality*, 2nd ed. New York, NY: Alba House. pp. 50-59).

[149] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2264, 2278; Grisez, G. 1977. Suicide and euthanasia. In *Death, Dying and Euthanasia*. edited by D. J. Horan and D. Mall, Washington, DC: University Publications of America, pp. 742-818; O'Donnell 1991. *op. cit.*, pp. 54, 57-59.

[150] John XXIII 1963. *op. cit.*, nos. 9, 28; O'Donnell 1991. *op. cit.*, p. 47; Wojyla 1981. *op. cit.*, pp. 24, 27.).

[151] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1731, 1777, 1782, 1788.

[152] John XXIII 1963. *op. cit.*, nos. 31-33; O'Donnell 1991. *op. cit.*, p. 47.

[153] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1782.

[154] DeVita, V. T., Jr., T. S. Lawrence, and S. A. Rosenberg. 2014. *Cancer Principles and Practice*, 10th Edition. Philadelphia: Wolters Kluwer Health/ Lippincott Williams & Wilkins.

[155] Bach 2014b, *loc. cit.*; Bach et al. 2012, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Salas-Vega and Mossialos 2016, *loc. cit.*

[156] Antolin, A. A., P. Workman, J. Mestres, and B. Al-Lazikani. 2016. Polypharmacology in precision oncology: Current applications and future prospects. *Current Pharmaceutical Design* 22(46): 6935-6945;

At the same time, prices continue to increase for many standard anti-cancer drugs as well as for the newer branded anti-cancer drugs.[157]

Unless the diagnosis is late or the progression of disease very aggressive, for most cancer patients the terminal illness comes after first-line and other standard therapies have been used and are no longer effective. Since cost-effectiveness is disallowed as a criterion for payment by government-legislated programs in the USA, it is unlikely that anti-cancer drugs, regardless of cost, could be withheld from cancer patients with disease that is progressing after treatment with generic agents;[158] though increasingly higher premiums for health insurance, co-insurance, and co-payments are leading to higher out-of-pocket patient costs.[159] Depending on the individual's economic circumstances and government or insurance coverage or lack thereof, this can mean quite different financial expenditures for individuals and different costs to government and insurance carriers.[160] Therefore, although judgments and decisions whether to undergo or forego treatment and to use very expensive drugs still lie solely with competent patients in the USA, the individual decisions of free subjects living in relationship with others do have economic effects for their families and their communities.

Human life is sacred.[161] From natural law and Scripture, it follows that intentionally killing an innocent person, including oneself, *always* is gravely wrong.[162] Ordinarily, the prolongation of an individual human life is right and virtuous.[163] Certainly, this would usually be true for persons diagnosed with cancer for whom without undue personal costs or burden to others, life may be extended by medical treatment with reasonable expectation of success and recovery.[164] When judged in relation to personal

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Fidler, I. J. 2012. Biological heterogeneity of cancer: Implication to therapy. *Human Vaccines & Immunotherapeutics* 8(8): 1141-1142; Frazier, J. P., J. A. Bertout, W. S. Kerwin, A. Moreno-Gonzalez, J. R. Casalini, M. O. Grenley, et al. 2017. Multidrug analyses in patients distinguish efficacious cancer agents based on both tumor cell killing and immunomodulation. *Cancer Research* 77(11): 2869-2880; Sievers, C. K., A. A. Leystra, L. Clipson, W. F. Dove, and R. B. Halberg. 2016. Understanding intratumoral heterogeneity: Lessons from the analysis of at-risk tissue and premalignant lesions in the colon. *Cancer Prevention Research* 9(8): 638-641; Wilting, R. H., and J. H. Dannenberg. 2012. Epigenetic mechanisms in tumorigenesis, tumor cell heterogeneity and drug resistance. *Drug Resistance Updates*: *Reviews and Commentaries in Antimicrobial and Anticancer Chemotherapy* 15(1-2): 21-38.

[157] Salas-Vega and Mossialos 2016, *loc. cit.*

[158] Brock 2010, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Neumann 2006, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*

[159] Brock 2010, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Zafar 2016, *loc. cit.*

[160] Bach 2009, *loc. cit.*; Brock 2010, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; MacLeod et al., *loc. cit.*; Pfister 2013, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Seabury et al. 2012, *loc. cit.*

[161] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2258, 2318, 2319; United States Conference of Catholic Bishops 2019. *op. cit.*

[162] Aquinas 2017. *op. cit.*, II-II, q. 64, a. 1-8; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2258-2265, 2268, 2280-2282, 2319, 2325; John Paul II 1993. *op. cit.*, nos. 59, 60; John Paul II 1995. *op. cit.*, nos. 57, 66-67; Kant 2019. *op. cit*, pp. 30-44.

[163] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2264, 2265, 2276, 2288.

[164] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2264, 2276, 2278, 2288; John Paul II 1995. *op. cit.*, no. 67; United States Conference of Catholic Bishops 2018. *op. cit.*, no. 56.

costs and the burdens on family and the community, cancer victims, who are stricken with terminal illness, gravitating toward death, and intelligently grasping the ultimate futility of treatment, may ethically choose ordinary care and refuse aggressive management, even if there is some hope for prolonging survival.[165]

Earthly human life is a fundamental, not an absolute good.[166] Pope Benedict XVI recently reminded that "There are values which must never be abandoned for a greater value and even surpass the preservation of physical life."[167, 168] Christianity is a brotherhood of martyrs, ordinary people giving true witness by their good works and love for others.[169]

Every ethical judgment is unique, and individual decisions regarding health and cancer care rightfully should be freely made by the patient, considering not only the effects and expense of treatment but also the intangible elements important to the individual, such as hope and sincere religious beliefs.[170] When considering the use of very expensive drugs, which may be in short supply, patients should judge the potential and probable effects of their decisions for family, other patients, and the economic community. In cases where funds are disbursed for expensive anti-cancer drugs in the disease's late stages with little expectation of improving the condition of a patient or significantly extending the patient's symptom-free survival, it could be a cancer patient's good moral judgment to distribute these resources to other patients for whom they can be more efficacious in promoting health and survival and, therefore, human dignity and the common good. Demands for treatment at huge expense can be contrary to the dignity of self and others and to the common good, especially if expectations for prolonging life are minimal and death is imminent.

From the perspective of human dignity and the common good and depending on circumstances, the moral subject for the sake of love and justice may judge it best to give up the use of an expensive drug in short supply for the good or others and the

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[165] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2278; John Paul II 1995. *op. cit.*, nos. 65, 86; O'Donnell 1991. *op. cit.*, p. 54; United States Conference of Catholic Bishops 2018. *op. cit.*, no. 57.

[166] Benedict XVI. 2019. The Church and the scandal of sexual abuse. *Catholic News Agency*. April 10. https://www.catholicnewsagency.com/news/full-text-of-benedict-xvi-the-church-and-the-scandal-of-sexual-abuse-59639 (accessed April 26, 2019); *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2258, 2263, 2265, 2288, 2289; John Paul II 1993. *op. cit.*, no. 50; John Paul II 1995. *op. cit.*, nos. 42, 47; Kelly, D. F., G. Magill, and H. ten Have. 2013. *Contemporary Catholic Health Care Ethics*. Washington, DC: Georgetown University Press. p. 128; Markwell, H. J. and B. F. Brown. 2008. Roman Catholic bioethics. In *The Cambridge Textbook of Bioethics*. edited by P. A. Singer and A. M. Viens, 436-445. New York: Cambridge University Press, 2008. p. 55.

[167] Benedict XVI 2019. *loc. cit.*

[168] Also see: John Paul II 1995. *op. cit.*, no. 2.

[169] Benedict XVI 2019. *loc cit.*; John Paul II 1995. *op. cit.*, nos. 49, 54, 55, 76, 77, 86, 87; Joseph, P. 2007. True and false martyrdom. *Catholic Culture.com.* May. https://www.catholicculture.org/culture/library/view.cfm?recnum=8633 (accessed April 29, 2019); Wojtyla 1981. *op. cit.*, pp. 28-31.

[170] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1782; Lakdawalla et al. 2012, *loc. cit*; Schnipper et al. 2015, *loc. cit.*

community at large.[171] No one has greater love than this, to lay down one's life for one's friends (John 15:13).

Value-Based Ethical Decisions

Freedom makes man a moral subject, and freedom to choose imposes a moral responsibility to do good.[172] But grounding the morality of personal and/or social decisions solely on an ethic of individual or collective choice would not consider other essential dimensions of personhood or the natural sources for moral judgment and promotes utilitarian and libertarian norms for judging the good or evil of human acts.[173] As exposed earlier in this essay, utilitarian and libertarian principles and norms for individual and collective judgments are also inconsistent with the virtues of justice and love, which should guide morally good decisions regarding health and cancer care.[174] Rather, it is posited that moral agents, i.e., patients, physicians, corporate and community leaders, policy-makers and shareholders, should use the ethical principles of human dignity and the common good when making decisions relating to the costs of cancer care and anti-cancer drugs.[175] The following examples present situations to consider for moral value judgments guided by love and justice and grounded in the personalistic ideals of human dignity and the common good.[176]

When evaluating options for chemotherapy in cancer care, the informed patient must morally decide first whether the values of treatment with an available anti-cancer drug reasonably exceed the disvalues of treatment or of foregoing treatment. This decision ordinarily would be made by considering the efficacy, toxicities, and costs of the treatment along with the patient's personal parameters of values and hopes and goals, integrating and prioritizing these factors within the essential dimensions of personhood.[177] For the sake of others and the common good, each individual patient needs to reconcile the inherent tension between his or her will, hopes, and intentions and the expenditure of resources that might be allocated to other good purposes, especially when the realistic expectation for prolongation of the person's own life is small and the

[171] Benedict XVI 2005. *op. cit.*, no. 30; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 288, 2289; John Paul II 1993. *op. cit.*, nos. 50, 94; John Paul II 1995. *op. cit.*, nos. 42-44, 48, 49, 52-55, 77, 86, 87; United States Conference of Catholic Bishops 2018, nos. 32, 56, 57; Wojtyla 1981. *op. cit.*, pp. 22-24, 28-31, 41-42, 119-120, 250.

[172] Aquinas 2017. *op. cit.*, I-II, q. 94, a. 2; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1749-1761, 1777-1783, 1786; John Paul II 1993. *op. cit.*, nos. 30-32, 43, 44, 54; Vatican Council II 1965. *op. cit.*, no. 16.

[173] Callahan 1994, *loc. cit.*; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1879-1881, 1905-1907; Kant 2019, *op. cit.*, pp. 26-58; Wojtyla 1981. *op. cit.*, pp. 22-28, 34-38, 54-55, 250.

[174] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1929-1932, 1912; Wojtyla 1981. *op. cit.*, pp. 35-42.

[175] Pontifical Council for Justice and Peace 2004. *op. cit.*, nos. 168, 169, 182.

[176] Wojtyla 1981. *op. cit.*, pp. 22-27, 41.

price for treatment is high.[178] Freely admitted, that is a tall order, especially for cancer patients with terminal illness, frequently in pain from the disease and debilitated from its treatment. Every decision entails interrelationships. So, even in dire circumstances, to the extent possible, patients should be in consultation with trusted friends, supportive counselors, their families, and their physicians.[179]

In the patient-physician relationship, the physician's first ethical and fiduciary duty is to the patient and not the physician's financial interest, nor the interest of an employer or of the State or an insurance carrier, nor the interest of science or a scientific body, if these are involved.[180] The physician's second professional ethical duty is to promote the common good with a "preferential option for care of the poor, the sick, and the rejected."[181]

Guided by charity and grounded in respect for the essential dimensions of personhood, physicians are obliged by the standards of their profession and their responsibilities to individual patients to be knowledgeable, current, and skilled in their specialties.[182] Professional expertise is basic for the best medical judgments, therapeutic recommendations, and honest counseling. Each patient is a unique, independent, inviolable subject presenting for competent advice and care. Studies have shown that besides their prognoses and the expected outcomes, efficacies, and untoward side effects of treatment choices, cancer patients want information also about the associated financial costs.[183] Oncologists and other physicians caring for cancer patients should be ready to respond honestly to patients' questions about the financial costs of their treatment or be able to direct their patients to financial advisors who can. The greatest help that physicians can provide is always accurate information and skillful treatment.

The caring physician should be able to explain frankly and meaningfully to patients the expected outcomes of alternative courses of management and therapy, including the relative costs for anti-cancer drug regimens and, when these are extravagant, provide an understanding of how equivalent resources might be applied to help others in need.[184] By virtue of their privileged knowledge of medicine, physicians should assist

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[177] Wojtyla 1981. *op. cit.*, pp. 22-24, 27, 54-55, 119-121, 250.

[178] Wojtyla 1981. *op. cit.*, pp. 24, 28-31, 38.

[179] Callahan 1994, *loc. cit.*; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1787, 1788.

[180] Ashley and O'Rourke 1997. *op. cit.*, pp. 93-97, 346-349; Benedict XVI. 2007a. Address to members of the International Congress of Catholic Pharmacists. October 29. http://w2.vatican.va/content/benedict-xvi/en/speeches/2007/october/documents/hf_ben-xvi_spe_20071029_catholic-pharmacists.html (accessed April 4, 2018); O'Donnell 1991. *op. cit.*, pp. 47, 105-111, 259-261; Pellegrino, E. D. 1990. The medical profession as a moral community. *Bulletin of the New York Academy of Medicine* 66(3): 221-232; Pellegrino, E. D. 1995. The human person, the physician, and the physician's ethics. *Linacre Quarterly* 62(1): 74-82; Pellegrino, E. D. 2012. Medical ethics in an era of bioethics: Resetting the medical profession's compass. *Theoretical Medicine and Bioethics* 33(1): 21-24.

[181] Pellegrino 1995. *loc. cit.*

[182] Ashley and O'Rourke 1997. *op. cit.*, p. 95; Pellegrino 1990. *loc. cit.*

[183] Lakdawalla et al. 2012, *loc. cit*; MacLeod et al., *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[184] Allan et al., *loc. cit.*

each patient toward management choices most likely to benefit the patient and the common good. When well-informed, discerning patients come to decisions regarding their own cancer care and use of drugs within the range of available resources, ultimate moral agency rests emphatically with the patient.[185] Unless a competent patient's choice for treatment is inconsistent with the physician's own ethical beliefs and/or harmful to the patient or others, the physician should support her or his patient's decision and continue to provide dignified care within the chosen parameters.[186]

Traditionally, physicians are their patients' advocates. It is not uncommon in the practice of medicine for physicians to find themselves to be the *only* advocates for the human welfare of their patients with hospital administrators and staff and far too often with third-party payers and institutional bureaucracies.[187] In their advocacy roles, physicians ought not to be confined to efforts for securing the welfare of their individual patients, but their goal should be also to advance the well-being of all patients, particularly the most needy.[188] Acting alone or together with colleagues through professional organizations, physicians can extend their advocacy by directing public and political attention to the present and growing high costs of anti-cancer drugs for patients and for society.[189]

These efforts, too, require moral judgments. Physicians and physicians' groups and their leadership must always be mindful of the dangers of becoming self-serving through the strengths gained by organizing.[190] Each physician is accountable for her or his engagement in group decisions and continued support of group activities.[191] No less than in personal decisions, the effects of group activity on the sacrosanct principles of human dignity, justice, and the common good with special concern for the disadvantaged should serve physician members of professional organizations when deliberating questions regarding opportunities, challenges, and action plans. It would not be right for patients, physicians, and advocacy groups to stand alone in defense of patients' prerogatives and in the quest for just distribution of healthcare resources.[192] Healthcare

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[185] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1730-1735, 1782, 1783.

[186] Pellegrino 1990. *loc. cit.*; Pellegrino 1995. *loc. cit.*

[187] *Ibid.*

[188] *Ibid.*

[189] American Society of Clinical Oncology. 2014. *op. cit.*; Daniel, H., and The Health and Public Policy Committee of the American College of Physicians. 2016. Stemming the escalating cost of prescription drugs: A position paper of the American College of Physicians. *Annals of Internal Medicine* 165(1): 50-52, Appendix. https://annals.org/pdfaccess.ashx?url=/data/journals/aim/935403/ (accessed May 3, 2017); Fleming, D. A. 2015. The moral agency of physician organizations: Meeting obligations to advocate for patients and the public. *Annals of Internal Medicine* 163(12): 918-921; Society of Gynecologic Oncology 2016, *op. cit.*

[190] Pellegrino 1990. *loc. cit.*; Pellegrino, E. D. 1999. The commodification of medical and health care: The moral consequences of a paradigm shift from a professional to a market ethic. *Journal of Medicine and Philosophy* 24(3): 243-266.

[191] Pellegrino 1990. *loc. cit.*

[192] Pontifical Council for Justice and Peace 2004. *op. cit.*, no. 167.

executives and pharmaceutical company officers, employees, and investors should recognize their own ethical obligations to patients and how the common good might be affected by their decisions.[193]

Each person's talents and relationships with others should be the impetus drawing her or him to a life's work, to a vocation.[194] Healing is the vocation to which physicians have committed themselves. Other healthcare workers and the employees of clinical operations, diagnostic laboratories, and pharmaceutical and medical device companies have chosen to work in a field whose goal is the healing of individual patients and overall health for their communities.[195] Corporate managers and executives producing pharmaceutical and medical devices bear special responsibilities to look after the good of all their stakeholders.[196] Officers at the highest levels of healthcare enterprises are charged with evaluating and balancing the likely effects of their decisions on the safe and fair accessibility of their services and/or products to all patients, including the most vulnerable, on just wages and advancement for their employees without favoritism, on furthering research and development, and on providing these goods and services with fair return on investment for stockholders in competitive environments.[197]

None of these goals can be achieved without profit. Without present and continuing or anticipated profit there is no service or product, no work, no discovery; and there will be losses for honest, well-meaning investors.[198] Even with not-for-profit enterprises, it is axiomatic that revenues must exceed expenses. Yet, if profits for pharmaceuticals can be maximized, this is not a claim that they should be maximized.[199] Profits from the production and distribution of anti-cancer drugs should be equitable and just, commensurate with profits gained in a free market from providing goods and services with similar risks and costs for human ingenuity, production, and material resources.[200]

Though inconsistent methods for wholesale distribution and controversial accounting practices can blur the amount of pharmaceutical company profits,[201] there is abundant empirical evidence that the pricing of some anti-cancer drugs has resulted

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[193] John XXIII 1963. *op. cit.*, no. 9.

[194] John XXIII 1963. *op. cit.*, no. 31; Vatican Council 1965. *op. cit.*, nos. 30, 75.

[195] Benedict XVI 2007a. *loc. cit.*

[196] Paul II 1991. *op. cit.*, nos. 34, 35; John Paul II. 2004. Message to the participants in the Conference on The Business Executive: Social Responsibility and Globalization, March 3. https://w2.vatican.va/content/john-paul-ii/en/speeches/2004/march/documents/hf_jp-ii_spe_20040305_martino.html (accessed April 4, 2018); Wojtyla 1981. *op. cit.*, pp. 26-30, 41-42.

[197] John XXIII 1961. *op. cit.*, no. 71; John Paul II 2004. *op. cit.*; Pius XII. 1957. In *The Pope Speaks: The Teachings of Pope Pius XII*. edited by M. Chinigo, New York: Pantheon. p. 309..

[198] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2432; Paul II 1991. *op. cit.*, no. 35; Pius XII. 1957. *op. cit.*, pp. 290-291, 309.

[199] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Prasad et al. 2017, *loc. cit.*; Reinhardt 2016. *loc. cit.*

[200] Benedict XVI. 2007b. Angelus. September 23. http://w2.vatican.va/content/benedict-xvi/en/angelus/2007/documents/hf_ben-xvi_ang_20070923.html (accessed April 4, 2018); Reinhardt 2016. *loc. cit.*

[201] DeAngelis 2016, *loc. cit.*; Reinhardt 2016. *loc. cit.*

in excessive profits for their producers.[202] Using estimates from data considered to be more complete than that furnished directly by major companies, researchers estimated that the proportion of revenue which USA pharmaceutical companies spent on marketing drugs far exceeded their expenditures for research and development.[203] The inordinate allocation of resources to promote the prescription and demand for expensive new branded drugs through intensively detailing physicians and direct mass media advertising to patients—a practice prohibited in all advanced countries apart from the USA and New Zealand—may increase company profits but neglect the pursuit of potential advancements in basic and pharmacologic sciences that might truly benefit patients in the long run.[204] In some cases, costs accounted to research and development may have been delegated to the acquisition of patents for marketable drugs or the purchase of other companies with products in development.[205]

Other ethically dubious, if legal, business practices used by pharmaceutical companies to maximize profits have been reported.[206]

Whereas, over regulation can stifle ingenuity and progress in business, science, and health care, an open market may invite unwarranted exploitation. Recent allegations of exorbitant drug pricing by several pharmaceutical companies highlight the need for greater transparency and executive accountability.[207] Especially when regulations are absent or lax, judicious managerial and corporate decisions and operations intended to do good and avoid evil depend on the well-informed conscience and on sound ethical grounding.[208]

Executive decisions can be risky, but attempting to maintain revenue streams and profits by raising drug prices to correct for poor ideas, bad managerial decisions, or a changing economic or regulatory environment, obscured accounting and financial reports, and marketing to increase the demand for products with higher acquisition costs

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[202] Anderson 2014. *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit*. Prasad et al. 2017, *loc. cit*.

[203] Gagnon, M-A., and J. Lexchin. 2008. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States. *PLoS Med* 5(1): e1; Sibley A. 2016. Health care's ills. *Linacre Quarterly* 83(4): 402-422.

[204] Anderson 2014, *loc. cit.*; Gagnon and Lexchin 2008. *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Sibley 2016. *loc. cit*.

[205] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit*.

[206] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Prasad et al. 2017, *loc. cit*.

[207] Murphy, H. 2019. Teva and other generic drugmakers inflated prices up to 1,000%, state prosecutors say. *The New York Times*. May 11. https://www.nytimes.com/2019/05/11/health/teva-price-fixing-lawsuit.html (accessed May 14, 2019); Saady, B. 2017. Why corporations are too big to jail in the drug war. *CounterPunch.org* February 17. https://www.counterpunch.org/2017/02/17/why-corporations-are-too-big-to-jail-in-the-drug-war/print/ (accessed May 14, 2019).

[208] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1749-1761, 1777, 1783; John Paul II 1993. *op. cit.*, nos. 29-32, 43-44.

but not significantly greater health benefits cannot be ethically justified.[209] Guided by justice and charity for all, business decisions should never be an assault to any person's human dignity. With great authority, comes great responsibility to work for the health of patients and seek the common good.[210]

Decisions for investing money, time, and effort in pharmaceuticals should involve reasoned judgments that are guided by justice and altruism and grounded in the ethical principles of human dignity and the common good. In the contemporary business climate, it is not uncommon for officers of pharmaceutical companies also to be company owners or to be rewarded for their performance with stock or stock options and remunerated memberships on other corporate boards. When the good and the value of health care are concerned, personal gain through financial incentives should not be factors considered in ethical executive decisions.[211]

Precisely because of their grave responsibilities to patients and caregivers, to constituents and stockholders, and to the community at large, business executives charged with the development, production, and distribution of anti-cancer drugs must conscientiously study and frankly consider, as far as possible, all contributing factors for the impact of their decisions on human dignity and the common good.[212]

Both for-profit and not-for-profit management decisions affect entire communities. Stockholders, their representatives and agents, and members of for-profit and not-for-profit corporate boards and trustees should not think of themselves as being so remote as to have no responsibilities for leadership decisions and obligations to the common good.[213] In free economic markets, reasonable returns can be anticipated from saving and investment and for risk-taking and the expenditure of time and talent.[214] Intangible rewards may result from volunteerism. But the expenditure of personal resources needs to be scrutinized in light of any forthcoming gains measured by excessive financial compensation and ego adulation.[215] Ownership, as a principal or holder of common stock, should be divested when the activities of a business firm are judged to be unscrupulous.[216] Likewise, resignation from membership on boards and trusteeships of for-profit

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[209] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[210] Paul II 1991. *op. cit.*, no. 32; John Paul II 2004. *op. cit.*

[211] Francis. 2013. Address to the Centesimus Annus Pro Pontifice Foundation. http://w2.vatican.va/content/francesco/en/speeches/2013/may/documents/papa-francesco_20130525_centesimus-annus-pro-pontifice.html (accessed April 4, 2018); John XXIII 1961. *op. cit.*, no. 81.

[212] John XXIII 1963. *op. cit.*, nos. 31-33; John Paul II 2004. *op. cit.*; Pius XII. 1957. *op. cit.*, pp. 307-312; Vatican Council II 1965. *op. cit.*, nos. 21, 26, 27, 29, 30, 69.

[213] Pius XII 1957. *op. cit.*, pp. 261, 301; United States Conference of Bishops 1986, *op. cit.*, nos. 13, 14, 18; United States Conference of Catholic Bishops. 2003. *Socially Responsible Investment Guidelines*. nos. 1, 2. http://www.usccb.org/about/financial-reporting/socially-responsible-investment-guidelines.cfm. (accessed October 16, 2019); Vatican Council II 1965. *op. cit.*, nos. 65, 72.

[214] Pius XII. 1957. *op. cit.*, pp. 290-291, 309.

[215] Francis. 2013. *op. cit.*; Pius XII. 1957. *op. cit.*, pp. 289-290.

[216] Hardon, J. A. 1996. Is it morally licit to invest in the stock market? *The Catholic Faith*. July/August. 2(4): 34.

and not-for-profit organizations that practice morally objectionable activity may serve as favorable examples in promotion of a common good; and the personal time and resources spent can be better used by upholding human dignity through virtuous support of the overall economy with special care for disadvantaged persons and groups.

Finally, when the intent is to promote healthfulness and to advance cancer prevention and cancer care, voters and rank-and-file members of organizations share corporate responsibility for studying, proposing, electing, and retaining representatives and leaders who share their values.[217] Responsible stewardship means that healthcare resources should be used judiciously and not squandered. The ideals of human dignity and the common good are advanced by securing autonomy for patients' own cancer care decisions and assuring fair access to the treatment that they choose. If the free market and individual moral agents are unable to accomplish these goals, voters and group members must work together with their elected representatives, leaders, and officials for laws and governmental regulations well-grounded in the principles of human dignity and the common good.[218] The valued principles of human dignity and the common good, which citizens hold dear, could be jeopardized by laws and regulations that *do not* fully consider, or even disregard, these values.[219] Well-studied, wise voting and representational political decisions are necessary to uphold just access and truly value-based use of anti-cancer drugs.

Conclusion

This article is not intended to present or conclude with a formula from which a cost or price for various anti-cancer drugs might be calculated based on measurable tangible outcomes and other factors meant to define the relative values for patients and/or the community. Rather, here are exposed the moral weaknesses and inconsistencies of such utilitarian approaches, if these were to be applied to real-life situations. This report, instead, examines value-based costing of anti-cancer drugs in an individual and societal framework and offers a model for moral judgments and decisions guided by justice and charity and grounded in the ethical principles of human dignity and the common good.

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[217] Benedict XVI 2005. *op. cit.*, nos. 28-29; John Paul II 1988. *op. cit.*, no. 42; John Paul II 1991. *op. cit.*, no. 47; Pius XII. 1957. *op. cit.*, p. 301; Vatican Council II 1965. *op. cit.*, nos. 69, 73-75, 93.

[218] Pius XII. 1957. *op. cit.*, p. 301; Pontifical Council for Justice and Peace 2004. *op. cit.*, nos, 168, 169, 190; Vatican Council II 1965. *op. cit.*, nos. 65, 66, 69-75.

[219] Pius XII. 1957. *op. cit.*, p. 301; Pontifical Council for Justice and Peace 2004, *op. cit.* no. 191.

Abortion Convictions Before Roe

Paul Benjamin Linton, J.D.[*]

As partisans on both sides of the abortion issue would acknowledge, there has been a spirited dispute as to the frequency with which violations of state statutes prohibiting abortion were prosecuted before *Roe v. Wade*[1] was decided in 1973. Without entering into that dispute,[2] this article provides the first comprehensive list of *pre-Roe* abortion (and abortion-related[3]) convictions that were affirmed on appeal, beginning with cases decided in the 1840s, and ending with a handful of convictions affirmed after *Roe* was decided in which the defendants were not licensed physicians. All of the prosecutions listed in this article were brought un-

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Mr. Linton has represented *amici curiae* in landmark beginning-of-life and end-of-life cases in the United States Supreme Court, including *Webster v. Reproductive Health Services* (1989), *Cruzan v. Director, Missouri Dep't of Health* (1990), *Planned Parenthood v. Casey* (1992), *Washington v. Glucksberg* (1997), *Vacco v. Quill* (1997), *Stenberg v. Carhart* (2000), *Ayotte v. Planned Parenthood of Northern New England* (2006), *Gonzales v. Oregon* (2000), *Gonzales v. Carhart* (2007) and *Gonzales v. Planned Parenthood Federation of America* (2007). He has also submitted briefs in most of the federal courts of appeals and a majority of the state supreme courts in the United States.

Mr. Linton has published two dozen law review articles on a variety of topics, including the history of abortion regulation and the Supreme Court's abortion jurisprudence, the legal status of unborn children under state law, state equal rights amendments, criminal law and procedure, sex discrimination, religious freedom claims and defenses under state constitutions and assisted suicide, as well as multiple articles in journals of opinion. He has also published the only comprehensive analysis of abortion rights claims under state constitutions, Abortion under State Constitutions *A State-by-State Analysis* (Carolina Academic Press) (3d ed. 2020). He received his undergraduate (B.A. Honors) and law (J.D.) degrees from Loyola University of Chicago.

[1] 410 U.S. 113 (1973).

[2] *See* Joseph W. Dellapenna, Dispelling the Myths of Abortion History (Carolina Academic Press 2006) at 490, 543-47, 673-74 for a discussion of the incidence of investigation and prosecution of abortionists. As Professor Dellapenna suggests, there likely would have been many more prosecutions were it not for the corruption of the police and prosecutors. *Id*. at 490 & n. 307, 543 & n. 46, 560, 674 & n. 289. He also debunks the notion, advanced by abortion advocates, that both physicians and lay persons who performed illegal abortions were able to practice openly without fear of arrest and prosecution. *Id*. at 489-90, 534, 558-64.

[3] Abortion-related convictions include convictions for murder or manslaughter based on the performance of (or attempt to perform) an illegal abortion.

der state statutes criminalizing abortion; the list does not include any prosecutions for the common law offense of abortion (statutory crimes gradually replaced common law crimes during the nineteenth century). In addition to the list of successful prosecutions (those affirmed on appeal), the article includes a chart showing the number of such prosecutions for each State for each decade from the 1840s to the 1970s, including cumulative totals for each State and each decade.

A few notes about the limitations of the data set forth below. The list of prosecutions does not include pleas of guilty that were not appealed (in those jurisdictions where such appeals are allowed), convictions after trial that were not appealed (more common earlier in our history than later) or appeals that were abandoned (and a number of the cases mentioned herein reference such appeals involving other defendants than those who pursued their own appeal). Inclusion of such information would increase the numbers of criminal convictions, perhaps significantly.[4] Nor does the list include proceedings by state medical boards to revoke, suspend or otherwise discipline licensed physicians (or other health care professionals) for performing illegal abortions. Because of the lower standard of proof in such cases (preponderance of the evidence rather than proof beyond a reasonable doubt, the standard applicable in criminal prosecutions), professional disciplinary proceedings may have offered an easier alternative, at least in some situations, to criminal prosecution where the underlying conduct involved licensed physicians.[5]

For the entire time frame covered (1840s to the early 1970s), the list includes 693 affirmed convictions. Of those, 184 (slightly more than 25%) were convictions for murder or manslaughter based on the performance of an illegal abortion. Of the total of 693 affirmed convictions, 266 (more than 38%) involved physicians (230), chiropractors (25), nurses (5), pharmacists (4) and dentists (2).[6] Physicians alone accounted for a third of all convictions.[7] In the twenty-five years before *Roe* was decided (1948–1973), there were 268 convictions, of which 94 (more than a third) involved physicians (79), chiropractors (11), nurses (2) and pharmacists (2). There were more than 100 affirmed convictions in each of the decades of the 1940s (107), 1950s (111) and 1960s (102) which, together with the thirty-six convictions affirmed in the early 1970s, account for more the one-half (356 of 693) of all affirmed convictions since the 1840s, thereby

[4] As Professor Dellapenna notes, "The data regarding the number of prosecutions is far from complete. At best, historians and others (myself included) have only surveyed the prosecutions that resulted in published court opinions plus occasional trial transcripts and newspaper accounts. This undoubtedly leaves a large number of prosecutions that have never been tallied in the attempt to assess the total number of prosecutions in any century—including the twentieth." Dispelling the Myths of Abortion History at 490.

[5] *Id.* at 535-36.

[6] The defendant in one case was a chiropractor who was also a nurse. He is included only in the chiropractor category.

[7] It should be noted that the opinions affirming convictions do not always indicate whether the defendant (or defendants) were health care professionals, so the percentage of convictions attributable to the conduct of physicians (and other health care professionals) might be higher.

demonstrating that there was no falling off in prosecutions as the country moved closer to the regime of abortion-on-demand mandated by *Roe*. Indeed, even after the effort to "liberalize" abortion statues began in 1967, culminating in thirteen States adopting one version or another of the Model Penal Code provision on abortion,[8] and four other States enacting abortion-on-demand statutes (at least until viability),[9] there were more than 60 convictions of both medical professionals and lay persons for performing abortions between 1967 and the early 1970s.

Interestingly, in the thirteen States that adopted one version of another of the Model Penal Code provision on abortion before *Roe*, beginning in 1967, no licensed physician was ever prosecuted and convicted for performing an abortion for a reason not permitted by the Code.[10] The absence of any prosecutions under the Model Penal Code provision for performing an abortion for a reason not allowed by the Code reinforces the notion that the exceptions, particularly the one for the pregnant woman's mental health, were completely elastic. That is confirmed by the experience under California's Therapeutic Abortion Act of 1967. According to data referenced by the California Supreme Court, more than 60,000 abortions were authorized and performed in 1970 for alleged "mental health" reasons, even though the standard for invoking the exception was the same as the standard for civil commitment, to wit, the pregnant woman had to pose a danger to herself or to others or to the property of others.[11] It is absurd to believe that more than 60,000 women met the standard for civil commitment merely because they were pregnant. It should be noted, moreover, that California was the only State that, before *Roe*, attempted to define the scope of the mental health exception, which suggests that the undefined mental health exceptions in the other States with abortion statutes based on the Model Penal Code were likely abused, as well.

It is the author's hope that the research set forth in this article will help to inform the ongoing debate over the history of abortion regulation in the United States.

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[8] The text of the Model Penal Code provision on abortion is set out in Appendix B to the Court's opinion in *Doe v. Bolton*, 410 U.S. 179,205-07 (1973), the companion case to *Roe*. Section 230.3 of the Model Penal Code permitted abortion if the attending physician believed that there was "substantial risk that continuance of the pregnancy would gravely impair the physical or mental health of the mother or that the child would be born with grave physical or mental defect, or that the pregnancy resulted from rape, incest, or other felonious intercourse."

[9] The statutes are cited in *Roe v. Wade*, 410 U.S. 113, 140 n. 37 (1973). The Court's inclusion of Mississippi in the list of States that adopted the Model Penal Code provision on abortion is questionable. In 1966, Mississippi added a rape exception to its life-of-the-mother statute, but none of the other exceptions set forth in the Model Penal Code (physical or mental health of the woman, incest or fetal anomaly).

[10] *But see Vuitch v. State*, 271 A.2d 371 (Md. Ct. Spec. App. 1970) (court affirming conviction of physician for performing an abortion outside of a hospital, as required by the Model Penal Code).

[11] *People v. Barksdale*, 503 P.2d 257, 265 (Cal. 1972).

Reported Appellate Court Decisions Affirming Pre-*Roe* Convictions for Abortion or Homicide Based on the Performance of an Illegal Abortion*

Alabama

Thomas v. State, 47 So. 257 (Ala. 1908) (abortion) (physician defendant)

Trent v. State, 73 So. 834 (Ala. Ct. App. 1916) (abortion)

Beard v. State, 88 So. 193 (Ala. Ct. App. 1920) (abortion)

Dykes v. State, 1 So.2d 754 (Ala. Ct. App. 1941) (abortion)

Hudson v. State, 9 So.2d 757 (Ala. Ct. App. 1942) (abortion)

Lingle v. State, 283 So.2d 660 (Ala. Crim. App. 1973) (abortion)

State v. Wilkerson, 305 So.2d 378 (Ala. Crim. App. 1974) (abortion)

Alaska

No reported cases affirming a conviction for abortion or an abortion related offense

Arizona

Kensey v. State, 65 P.2d 1141 (Ariz. 1937) (murder by illegal abortion)

Hightower v. State, 158 P.2d 156 (Ariz. 1945) (abortion) (physician defendant)

State v. Boozer, 291 P.2d 786 (Ariz. 1955) (abortion) (physician defendant)

Arkansas

Burris v. State, 84 S.W. 723 (Ark. 1904) (abortion)

Davis v. State, 130 S.W. 547 (Ark. 1910) (abortion)

Dawson v. State, 180 S.W. 761 (Ark. 1915) (manslaughter by killing a quick unborn child)

Thompson v. State, 260 S.W. 723 (Ark. 1924) (abortion)

Clayton v. State, 55 S.W.2d 88 (Ark. 1932) (abortion)

McClure v. State, 215 S.W.2d 524 (Ark, 1948) (abortion) (physician defendant)

* The term "abortion," when used to describe the offense of which the defendant was convicted, includes abortion (whether the defendant was charged as a principal or an accessory), attempted abortion and conspiracy to commit abortion. The list includes six post-*Roe* decisions from four States—Alabama, Arkansas, New Jersey and New York—affirming the convictions of defendants who were not physicians for performing abortions before *Roe*).

Mullins v. State, 401 S.W.2d 9 (Ark. 1960) (murder by illegal abortion)

Heath v. State, 459 S.W.2d 420 (Ark. 1970) (abortion)

May v. State, 492 S.W.2d 888 (Ark, 1973) (abortion)

California

People v. Balkwell, 76 P. 1017 (Cal. 1904) (murder by illegal abortion)

People v. Huntington, 97 P. 760 (Cal. Ct. App. 1908) (manslaughter by illegal abortion) (physician defendant)

People v. Thompson, 117 P. 1033 (Cal. Ct. App. 1911) (murder by illegal abortion)

People v. Richardson, 120 P. 21 (Cal. 1911) (abortion)

People v. Brewer, 127 P. 808 (Cal. Ct. App. 1912) (murder by illegal abortion)

People v. Simon, 131 P. 102 (Cal. Ct. App. 1913) (abortion)

People v. Watson, 132 P. 836 (Cal. Ct. App. 1913) (abortion) (physician defendant)

People v. Guaragna, 137 P. 279 (Cal. Ct. App. 1913) (abortion)

People v. Wright, 138 P. 349 (Cal. 1914) (manslaughter by illegal abortion) (physician defendant)

People v. Hunt, 147 P. 476 (Cal. Ct. App. 1915) (manslaughter by illegal abortion) (physician defendant)

People v. Gibson, 166 P. 585 (Cal. Ct. App. 1917) (murder by illegal abortion)

People v. Card, 180 P. 53 (Cal. Ct. App. 1919) (murder by illegal abortion) (physician defendant)

People v. Gilman, 185 P. 310 (Cal. Ct. App. 1919) (abortion) (nurse defendant)

People v. Northcott, 189 P. 704 (Cal. Ct. App. 1920) (murder by illegal abortion) (physician defendant)

People v. Thomas, 197 P. 677 (Cal. Ct. App. 1921) (murder by illegal abortion) (physician defendant)

People v. Hickok, 204 P. 555 (Cal. Ct. App. 1921) (abortion) (physician defendant)

People v. Morani, 236 P. 135 (Cal. 1925) (murder by illegal abortion)

People v. Schafer, 247 P. 576 (Cal. 1926) (murder by illegal abortion)

People v. Lee, 252 P. 763 (Cal. Ct. App. 1927) (abortion)

People v. Seiffert, 253 P. 189 (Cal. Ct. App. 1927) (murder by illegal abortion) (physician defendant)

People v. Watanebe, 266 P. 1000 (Cal. Ct. App. 1928) (murder by illegal abortion) (pharmacist defendant)

People v. Cook, 269 P. 176 (Cal. Ct. App. 1928) (murder by illegal abortion)

People v. Mount, 269 P. 177 (Cal. Ct. App. 1928) (manslaughter by illegal abortion) (chiropractor defendant)

People v. McKenney, 292 P. 135 (Cal. Ct. App. 1930) (abortion)

People v. Darrow, 298 P. 1 (Cal.1931) (murder by illegal abortion) (physician defendant)

People v. Browning, 22 P.2d 784 (Cal. Ct. App. 1933) (abortion)

People v. De Vaughn, 38 P.2d 192 (Cal. Ct. App. 1934) (murder by illegal abortion) (physician defendant)

People v. Collins, 40 P.2d 542 (Cal. Ct. App. 1935) (abortion) (chiropractor defendant)

People v. Knowles, 46 P.2d 788 (Cal. Ct. App. 1935) (murder by illegal abortion)

People v. Coltrin, 55 P.2d 1161 (Cal. 1936) (abortion, murder by illegal abortion) (physician defendant)

People v. Luckett, 73 P.2d 658 (Cal. Ct. App. 1937) (abortion)

People v. Rankin, 74 P.2d 71 (Cal. 1937) (abortion)

People v. Lorraine, 81 P.2d 1004 (Cal. Ct. App. 1938) (abortion)

People v. Hickok, 83 P.2d 39 (Cal. Ct. App. 1938) (murder by illegal abortion) (chiropractor defendant)

People v. Parchen, 98 P.2d 1045 (Cal. Ct. App. 1940) (abortion, murder by illegal abortion) (chiropractor defendant)

People v. Long, 103 P.2d 969 (Cal. 1940) (manslaughter by illegal abortion) (physician defendant)

People v. Wilson, 129 P.2d 149 (Cal. Ct. App. 1942) (murder by illegal abortion)

People v. Marineau, 132 P.2d 22 (Cal. Ct. App. 1942) (abortion) (chiropractor defendant)

People v. Smitherman, 135 P.2d 674 (Cal. Ct. App. 1943) (abortion, murder by illegal abortion)

People v. Garner, 140 P.2d 146 (Cal. Ct. App. 1943) (abortion) (physician defendant)

People v. Wilson, 153 P.2d 720 (Cal. 1944) (abortion)

People v. Clapp, 153 P.2d 758 (Cal. Ct. App. 1944) (murder by illegal abortion) (chiropractor defendant)

People v. Thompson, 158 P.2d 213 (Cal. Ct. App. 1945) (abortion) (chiropractor defendant)

People v. Alvarez, 166 P.2d 896 (Cal. Ct. App. 1946) (abortion)

People v. Emery, 179 P.2d 843 (Cal. Ct. App. 1947) (abortion) (physician defendant)

People v. Collins, 182 P.2d 585 (Cal. Ct. App. 1947) (abortion, homicide by abortion) (chiropractor defendant)

People v. Malone, 185 P.2d 870 (Cal. Ct. App. 1947) (abortion) (chiropractor/nurse defendant)

People v. Ramsey, 189 P.2d 802 (Cal. Ct. App. 1948) (abortion)

People v. Burns, 189 P.2d 868 (Cal. Ct. App. 1948) (abortion)

People v. Stone, 202 P.2d 333 (Cal. Ct. App. 1949) (abortion) (physician defendants)

People v. Garcia, 202 P.2d 762 (Cal. Ct. App. 1949) (abortion)

People v. Anderson, 202 P.2d 1044 (Cal. Ct. App. 1949) (abortion)

People v. Powell, 208 P.2d 974 (Cal. 1949) (abortion, manslaughter by illegal abortion) (chiropractor defendant)

People v. Rhoades, 209 P.2d 33 (Cal. Ct. App. 1949) (abortion)

People v. Miner, 214 P.2d 557 (Cal. Ct. App. 1950) (abortion) (chiropractor defendants)

People v. Raffington, 220 P.2d 967 (Cal. Ct. App. 1950) (abortion)

People v. Kirk, 220 P.2d 976 (Cal. Ct. App. 1950) (abortion)

People v. King, 231 P.2d 156 (Cal. Ct. App. 1951) (abortion) (chiropractor defendant)

People v. Allen, 231 P.2d 896 (Cal. Ct. App. 1951) (abortion) (physician defendant, nurse defendant)

People v. Von Mullendorf, 242 P.2d 403 (Cal. Ct. App. 1952) (abortion) (physician defendant)

People v. Morris, 243 P.2d 66 (Cal. Ct. App. 1952) (abortion) (physician defendant)

People v. Kendall, 244 P.2d 418 (Cal. Ct. App. 1952) (abortion) (unlicensed physician defendant)

People v. Green, 245 P.2d 526 (Cal. Ct. App. 1952) (abortion) (physician defendant)

People v. Reimringer, 253 P.2d 756 (Cal. Ct. App. 1953) (abortion) (physician defendant)

People v. Fowler, 260 P.2d 89 (Cal. Ct. App. 1953) (abortion) (physician defendant)

People v. Califro, 261 P.2d 332 (Cal. Ct. App. 1953) (abortion)

People v. Vosburg, 266 P.2d 927 (Cal. Ct. App. 1954) (abortion)

People v. Sherman, 273 P.2d 611 (Cal. Ct. App. 1954) (abortion) (physician defendant)

People v. Reed, 275 P.2d 633 (Cal. Ct. App. 1954) (abortion) (physician defendant)

People v. Berger, 275 P.2d 799 (Cal. Ct. App. 1954) (abortion)

People v. Davis, 276 P.2d 801 (Cal. 1954) (abortion) (physician defendant)

People v. Davis, 284 P.2d 496 (Cal. Ct. App. 1955) (abortion) (physician defendant)

People v. Bowlby, 287 P.2d 547 (Cal. Ct. App. 1955) (abortion) (chiropractor defendant)

People v. Berger, 280 P.2d 136 (Cal. Ct. App. 1955) (abortion) (physician defendant)

People v. Holbrook, 288 P.2d 1 (Cal. 1955) (abortion) (chiropractor defendant)

People v. Coghlan, 290 P.2d 879 (Cal. Ct. App. 1955) (abortion)

People v. Terrell, 291 P.2d 155 (Cal. Ct. App. 1955) (abortion) (chiropractor defendant)

People v. Escobedo, 292 P.2d 230 (Cal. Ct. App. 1956) (abortion)

People v. Brenon, 292 P.2d 645 (Cal. Ct. App. 1956) (murder by illegal abortion) (physician defendant)

People v. Cummings, 296 P.2d 610 (Cal. Ct. App. 1956) (abortion) (physician defendant)

People v. Karman, 303 P.2d 71 (Cal. Ct. App. 1956) (abortion)

People v. Ames, 312 P.2d 1111 (Cal. Ct. App. 1957) (abortion) (physician defendant)

People v. Dorn, 314 P.2d 1017 (Cal. Ct. App. 1957) (abortion) (physician defendant)

People v. MacEwing, 317 P.2d 82 (Cal. Ct. App. 1957) (abortion) (physician defendant)

People v. Curry-Allen, 318 P.2d 549 (Cal. Ct. App. 1957) (abortion) (physician defendant)

People v. Brown, 320 P.2d 5 (Cal. 1958) (abortion, murder by illegal abortion) (physician defendant)

People v. Ramsey, 320 P.2d 592 (Cal. Ct. App. 1958) (abortion)

People v. Daily, 321 P.2d 469 (Cal. Ct. App. 1958) (abortion)

People v. Odmann, 325 P.2d 495 (Cal. Ct. App. 1958) (murder by illegal abortion) (physician defendant)

People v. Weiss, 327 P.2d 527 (Cal. 1958) (abortion) (physician defendant)

People v. Barkoff, 329 P.2d 1005 (Cal. Ct. App. 1958) (abortion) (physician defendant)

People v. Stuart, 335 P.2d 192 (Cal. Ct. App. 1959) (abortion) (chiropractor defendant)

People v. Rivers, 340 P.2d 648 (Cal. Ct. App. 1959) (abortion) (pharmacist defendant)

People v. Malone, 343 P.2d 333 (Cal. Ct. App. 1959) (abortion)

People v. Feigin, 345 P.2d 273 (Cal. Ct. App. 1959) (abortion) (physician defendant)

People v. Hawkins, 2 Cal. Rptr. 524 (Cal. Ct. App. 1960) (abortion, murder by illegal abortion)

People v. Wilkes, 2 Cal. Rptr. 594 (Cal. Ct. App. 1960) (abortion) (chiropractor defendant)

People v. Vigil, 3 Cal. Rptr. 479 (Cal. Ct. App. 1960) (abortion)

People v. Clemons, 6 Cal. Rptr. 727 (Cal. Ct. App. 1960) (abortion)

People v. Kutz, 9 Cal. Rptr. 626 (Cal. Ct. App. 1960) (abortion)

People v. Reed, 10 Cal. Rptr. 536 (Cal. Ct. App. 1961) (abortion) (physician defendant)

People v. Struve, 12 Cal. Rptr. 47 (Cal. Ct. App. 1961) (abortion)

People v. Emory, 13 Cal. Rptr. 889 (Cal. Ct. App. 1961) (murder by illegal abortion)

People v. Tideman, 370 P.2d 1007 (Cal. 1962) (murder by illegal abortion)

People v. Bawden, 25 Cal. Rptr. 368 (Cal. Ct. App. 1962) (abortion)

People v. Pearl, 27 Cal. Rptr. 664 (Cal. Ct. App. 1963) (abortion)

People v. Kendall, 28 Cal. Rptr. 53 (Cal. Ct. App. 1963) (abortion) (unlicensed physician defendant)

People v. Moore, 28 Cal. Rptr. 530 (Cal. Ct. App. 1963) (abortion) (physician defendant)

People v. Cross, 28 Cal. Rptr. 918 (Cal. Ct. App. 1963) (abortion)

People v. Pheaster, 30 Cal. Rptr. 363 (Cal. Ct. App. 1963) (abortion)

People v. MacEwing, 30 Cal. Rptr. 476 (Cal. Ct. App. 1963) (abortion) (physician defendant)

People v. Shead, 30 Cal. Rptr. 580 (Cal. Ct. App. 1963) (abortion) (physician defendant)

People v. Jackson, 31 Cal. Rptr. 356 (Cal. Ct. App. 1963) (abortion, murder by illegal abortion) (physician defendant)

People v. Flynn, 31 Cal. Rptr. 651 (Cal. Ct. App. 1963) (abortion)

People v. Singer, 32 Cal. Rptr. 701 (Cal. Ct. App. 1963) (abortion) (physician defendant)

People v. Reinhard, 33 Cal. Rptr. 908 (Cal. Ct. App. 1963) (abortion) (physician defendant)

People v. Chamberlin 51 Cal. Rptr. 679 (Cal. Ct. App. 1966) (abortion)

People v. Root, 55 Cal. Rptr. 89 (Cal. Ct. App. 1966) (abortion)

People v. Kramer, 66 Cal. Rptr. 638 (Cal. Ct. App. 1968) (abortion) (physician defendant)

People v. Marshall. 78 Cal. Rptr. 16 (Cal. Ct. App. 1969) (manslaughter by illegal abortion)

Colorado

Daugherty v. People, 1 Colo. 514 (1872) (abortion)

Solander v. People, 2 Colo. 48 (1873) (murder by illegal abortion)

Johnson v. People, 80 P. 133 (Colo. 1905) (abortion and murder by illegal abortion)

Fitch v. People, 100 P. 1132 (Colo. 1909) (abortion)

Marmaduke v. People, 101 P. 337 (Colo. 1909) (abortion)

Ausmus v. People, 107 P. 204 (Colo. 1910) (murder by illegal abortion)

Hamilton v. People, 165 P. 761 (Colo. 1917) (abortion) (physician defendant)

Willis v. People, 215 P. 854 (Colo. 1923) (murder by illegal abortion) (physician defendant)

Max v. People, 240 P. 697 (Colo. 1925) (murder by illegal abortion) (physician defendant)

Duncan v. People, 262 P. 918 (Colo. 1927) (murder by illegal abortion) (physician defendant)

Cowles v. People, 110 P.2d 249 (Colo. 1940) (murder by illegal abortion) (physician defendant)

Bashford v. People, 135 P.2d 516 (Colo. 1943) (abortion)

Montgomery v. People, 184 P.2d 480 (Colo. 1947) (abortion) (chiropractor defendant)

Wolf v. People, 187 P.2d 926 (Colo. 1947) (abortion) (one physician defendant, one chiropractor defendant)

Wolf v. People, 187 P.2d 928 (Colo. 1947) (abortion) (physician defendant)

Ferguson v. People, 192 P.2d 523 (Colo. 1948) (murder by illegal abortion)

Hall v. People, 201 P.2d 382 (Colo. 1948) (abortion) (chiropractor defendant)

Stewart v. People, 419 P.2d 650 (Colo. 1966) (abortion)

Palmer v. State, 424 P.2d 766 (Colo. 1967) (abortion)

Caraway v. People, 486 P.2d 17 (Colo. 1971) (abortion)

Connecticut

State v. Lee, 37 A. 75 (Conn. 1897) (abortion)

State v. Carey, 56 A. 632 (Conn. 1904) (abortion)

State v. Rankin, 127 A. 916 (Conn. 1925) (abortion)

State v. Yochelman, 139 A. 632 (Conn. 1927) (manslaughter by illegal abortion)

State v. Horwitz, 142 A. 470 (Conn. 1928) (abortion)

State v. Santoro, 22 A.2d 793 (Conn. 1941) (abortion)

State v. Orsini, 232 A.2d 907 (Conn. 1967) (abortion)

Delaware

Zutz v. State, 160 A.2d 727 (Del. 1960) (abortion) (defendant physician)

Florida

Eggart v. State, 25 So. 144 (Fla. 1898) (abortion)

Robertson v. State, 60 So. 118 (Fla. 1912) (manslaughter by illegal abortion)

McDonald v. State, 70 So. 24 (Fla. 1915) (abortion)

Graham v. State, 16 So.2d 59 (Fla. 1943) (abortion)

Urga v. State, 20 So.2d 685 (Fla. 1944) (abortion)

Weathers v. State, 56 So. 2d 536 (Fla. 1952) (abortion)

Sinnefia v. State, 100 So.2d 837 (Fla. Dist. Ct. App. 1958) (manslaughter by illegal abortion)

Nations v. State, 145 So.2d 259 (Fla. Dist. Ct. App. 1962) (abortion)

Urga v. State, 155 So.2d 719 (Fla. Dist. Ct. App. 1963) (abortion)

Carter v. State, 155 So.2d 787 (Fla. 1963) (abortion) (chiropractor defendant)

Cole v. State, 156 So.2d 185 (Fla. Dist. Ct. App. 1963) (abortion) (physician defendant)

Pessolino v. State, 161 So.2d 237 (Fla. Dist. Ct. App. 1964) (abortion) (physician defendant)

Pessolino, v. State, 166 So.2d 706 (Fla. Dist. Ct. App. 1964) (abortion) (physician defendant)

Carr v. State, 174 So.3d 449 (Fla. Dist. Ct. App. 1965) (abortion)

Jones v. State, 234 So.3d 736 (Fla. Dist. Ct. App. 1970) (abortion)

Georgia

Sullivan v. State, 48 S.E. 949 (Ga. 1904) (abortion)

Barrow v. State, 48 S.E. 950 (Ga. 1904) (abortion)

Gullatt v. State, 80 S.E. 340 (Ga. Ct. App. 1913) (abortion)

Summerlin v. State, 103 S.E. 830 (Ga. Ct. App. 1920) (manslaughter by illegal abortion)

Hunter v. State, 119 S.E. 704 (Ga. Ct. App. 1923) (abortion)

Herndon v. State, 142 S.E. 695 (Ga. Ct. App. 1928) (manslaughter by illegal abortion)

Wilbanks v. State, 152 S.E. 619 (Ga. Ct. App. 1930) (manslaughter by illegal abortion)

Fields v. State, 167 S.E. 337 (Ga. Ct. App. 1932) (abortion) (physician defendant)

Guiffrida v. State, 7 S.E.2d 34 (Ga. Ct. App. 1940) (abortion) (physician defendant)

Soldaat v. State, 57 S.E.2d 705 (Ga. Ct. App. 1950) (abortion)

Biegun v. State, 58 S.E.2d 149 (Ga. 1950) (murder by illegal abortion)

Holloway v. State, 82 S.E.2d 235 (Ga. Ct. App. 1954) (abortion)

Persons v. State, 91 S.E.2d 358 (Ga. Ct. App. 1956) (manslaughter by illegal abortion)

White v. State, 151 S.E.2d 832 (Ga. Ct. App. 1966) (manslaughter by illegal abortion)

Scott v. State, 176 S.E.2d 481 (Ga. Ct. App. 1970) (abortion)

Griffin v. State, 182 S.E.2d 498 (Ga. Ct. App. 1971) (abortion)

Hawaii

Territory v. Hart, 35 Haw. 582 (1940) (abortion and manslaughter by illegal abortion)

Territory v. Young, 37 Haw. 150 (1945) (abortion) (physician defendant)

Territory v. Young, 37 Haw. 189 (1945) (abortion and murder by illegal abortion) (one physician defendant, one nurse defendant)

Territory v. Decorian, 38 Haw. 121 (1948) (abortion)

Idaho

State v. Alcorn, 64 P. 1014 (Idaho 1901) (manslaughter by illegal abortion) (physician defendant)

State v. Rose, 267 P.2d 109 (Idaho 1954) (abortion)

Illinois

Holliday v. People, 9 Ill. 110 (1847) (abortion)

Armstrong v. People, 37 Ill. 459 (1865) (abortion)

Earll v. People, 73 Ill. 329 (1874) (manslaughter by illegal abortion) (physician defendant)

Beasley v. People, 89 Ill. 571 (1878) (murder by illegal abortion)

Earll v. People, 99 Ill. 123 (1881) (abortion) (physician defendant)

Scott v. People, 30 N.E. 329 (Ill. 1892) (abortion)

Cook v. People, 52 N.E. 273 (Ill. 1898) (manslaughter by illegal abortion)

Howard v. People, 57 N.E. 441 (Ill. 1900) (manslaughter by illegal abortion)

Hagenow v. People, 59 N.E. 242 (Ill, 1900) (manslaughter by illegal abortion) (physician defendant)

Clark v. People, 79 N.E. 941 (Ill. 1906) (murder by illegal abortion)

People v. Buettner, 84 N.E.218 (Ill. 1908) (manslaughter by illegal abortion) (physician defendant)

People v. Hagenow, 86 N.E. 370 (Ill. 1908) (homicide by illegal abortion)

People v. Dennis, 92 N.E. 964 (Ill. 1910) (abortion)

People v. Hotz, 103 N.E. 1007 (Ill. 1913) (murder by illegal abortion)

People v. Patrick, 115 N.E. 390 (Ill. 1917) (abortion)

People v. Carrico, 142 N.E. 164 (Ill. 1923) (manslaughter by illegal abortion) (physician defendant)

People v. Pigatti, 145 N.E. 608 (Ill. 1924) (abortion)

People v. Zwienczak, 170 N.E. 303 (Ill. 1930) (murder by illegal abortion)

People v. Heissler, 170 N.E. 685 (Ill. 1930) (homicide by illegal abortion)

People v. Stilson, 174 N.E. 45 (Ill. 1930) (murder by illegal abortion) (physician defendant)

People v. Rongetti, 176 N.E. 298 (Ill. 1931) (manslaughter by illegal abortion) (physician defendant)

People v. Ney, 181 N.E. 595 (Ill. 1932) (murder by illegal abortion) (physician defendant)

People v. Kreutzer, 188 N.E. 422 (Ill. 1933) (manslaughter by illegal abortion)

People v. Valentino, 188 N.E. 825 (Ill, 1933) (murder by illegal abortion)

People v. Mitchell, 14 N.E.2d 216 (Ill. 1938) (manslaughter by illegal abortion) (physician defendant)

People v. Schneider, 19 N.E.2d 748 (Ill. 1939) (chiropractor defendant)

People v. Schyman, 29 N.E.2d 270 (Ill. 1940) (abortion) (physician defendant)

People v. Martin, 34 N.E.2d 845 (Ill. 1941) (murder by illegal abortion) (physician defendant)

People v. Schaffner, 46 N.E.2d 989 (Ill. 1943) (manslaughter by illegal abortion) (physician defendant)

People v. Gleitsman, 51 N.E.2d 261 (Ill. 1943) (murder by illegal abortion) (physician defendant)

People v. Pavluk, 54 N.E.2d 567 (Ill. 1944) (manslaughter by illegal abortion) (physician defendant)

People v. Nathanson, 59 N.E.2d 677 (Ill. 1945) (abortion) (physician defendant)

People v. Young, 75 N.E.2d 349 (Ill. 1947) (abortion) (physician defendant)

People v. Khamis, 103 N.E.2d 133 (Ill. 1951) (abortion) (physician defendant)

People v. Tilley, 104 N.E.2d 499 (Ill. 1952) (manslaughter by illegal abortion)

People v. Kalpak, 140 N.E.2d 726 (Ill. 1957) (abortion)

People v. Heidman, 144 N.E.2d 580 (Ill. 1957) (abortion)

People v. Woods, 180 N.E.2d 475 (Ill. 1962) (abortion)

People v. Sarelli, 180 N.E.2d 722 (Ill. App. Ct. 1962) (abortion)

People v. Gomez, 194 N.E.2d 299 (Ill. 1963) (abortion)

People v. Johndrow, 218 N.E.2d 25 (Ill. App. Ct. 1966) (abortion)

People v. Babitsch, 226 N.E.2d 469 (Ill. App. Ct. 1967) (abortion)

People v. Fulton, 228 N.E.2d 203 (Ill. App. Ct. 1967) (abortion) (pharmacist defendant)

People v. Heidman, 231 N.E.2d 457 (Ill, 1967) (abortion)

People v. Hoffmann, 260 N.E.2d 351 (Ill. App. Ct. 1970) (abortion)

People v. West, 262 N.E.2d 323 (Ill. App. Ct. 1970) (abortion)

Indiana

Carter v. State, 2 Ind. 617 (1851) (abortion)

Hensley v. State, 8 N.E. 692 (Ind. 1886) (abortion)

Hauk v. State, 46 N.E. 127 (Ind. 1887) (abortion)

McCaughey v. State, 59 N.E. 169 (Ind. 1901) (abortion)

Carter v. State, 87 N.E. 1081 (Ind. 1909) (abortion)

Thain v. State, 106 N.E. 690 (Ind. 1914) (abortion) (physician defendant)

Murphy v. State, 110 N.E. 198 (1915) (abortion)

State v. Jackson, 121 N.E. 114 (Ind. 1918) (abortion)

Hill v. State, 141 N.E. 639 (Ind. 1923) (abortion) (physician defendant)

Pleak v. State, 167 N.E. 524 (Ind. 1924) (abortion) (physician defendant)

Sharp v. State, 19 N.E.2d 942 (Ind. 1939) (abortion) (physician defendant)

Waltermire v. State, 59 N.E.2d 123 (Ind. 1945) (abortion) (physician defendant)

Grecu v. State, 120 N.E.2d 179 (Ind. 1954) (abortion) (physician defendant)

Specht v. State, 163 N.E.2d 581 (Ind. 1960) (abortion)

Cheaney v. State, 285 N.E.2d 265 (Ind. 1972) (abortion)

Iowa

State v. Moore, 25 Iowa 128 (1868) (murder by illegal abortion) (physician defendant)

State v. Hollenbeck, 36 Iowa 112 (1872) (abortion)

State v. Thurman, 24 N.W. 511 (Iowa 1885) (murder by illegal abortion)

State v. Montgomery, 33 N.W. 143 (Iowa 1887) (abortion)

State v. Minard, 65 N.W. 147 (Iowa 1895) (murder by illegal abortion)

State v. Smith, 68 N.W. 428 (Iowa 1896) (abortion) (physician defendant)

State v. Crofford, 110 N.W. 921 (Iowa 1907) (murder by illegal abortion) (physician defendant)

State v. Stafford, 123 N.W. 167 (Iowa 1909) (abortion)

State v. Barrett, 198 N.W. 36 (Iowa 1924) (abortion)

State v. Rowley, 198 N.W. 37 (Iowa 1924) (abortion)

State v. Rowley, 248 N.W. 350 (Iowa 1933) (abortion)

State v. Anderson, 33 N.W.2d 1 (Iowa 1948) (murder by illegal abortion) (physician defendant)

State v. Snyder, 59 N.W.2d 223 (Iowa 1953) (abortion) (physician defendant)

State v. Abodeely, 179 N.W.2d 347 (Iowa 1970) (abortion)

Kansas

State v. Watson, 1 P. 770 (Kan. 1883) (abortion)

State v. Kesner, 82 P. 720 (Kan. 1905) (manslaughter by illegal abortion) (physician defendant)

State v. Hatch, 112 P. 149 (Kan. 1910) (abortion)

State v. Harris, 136 P. 264 (Kan. 1913) (manslaughter by illegal abortion)

State v. Patterson, 181 P. 609 (Kan. 1919) (manslaughter by illegal abortion) (physician defendant)

State v. Nossaman, 243 P. 326 (Kan. 1926) (manslaughter by illegal abortion) (physician defendant)

State v. Brown, 236 P.2d 59 (Kan. 1951) (manslaughter by illegal abortion)

State v. Darling, 493 P.2d 216 (Kan. 1972) (abortion)

Kentucky

Peoples v. Commonwealth, 9 S.W. 509 (Ky. 1888) (manslaughter by illegal abortion)

Fitch v. Commonwealth, 165 S.W.2d 558 (Ky, 1942) (abortion) (physician defendant)

Richardson v. Commonwealth, 312 S.W.2d 47 (Ky, 1958) (abortion)

Dalzell v. Commonwealth, 312 S.W.2d 354 (Ky. 1958) (abortion)

Bain v. Commonwealth, 330 S.W.2d 400 (Ky, 1959) (abortion)

Lewis v. Commonwealth, 332 S.W.2d 656 (Ky. 1959) (abortion) (physician defendant)

Brown v. Commonwealth, 440 S.W.2d 520 (Ky, 1969) (abortion)

Sasaki v. Commonwealth, 485 S.W.2d 897 (Ky. 1972) (abortion) (physician defendant), *vacated and remanded*, 410 U.S. 951 (1973)

Louisiana

State v. Paillet, 165 So.2d 294 (La. 1964) (abortion)

State v. Sharp, 182 So.2d 517 (La. 1966) (abortion)

State v. Reese, 194 So.2d 729 (La. 1967) (manslaughter by illegal abortion)

State v. Pesson, 235 So.2d 568 (La. 1970) (abortion)

State v. Shirley, 238 So.2d 676 (La. 1970) (abortion)

State v. Scott, 255 So.2d 736 (La. 1971) (abortion)

Maine

State v. Dyer, 59 Me. 303 (1871) (abortion) (physician defendant)

State v. Means, 50 A. 30 (Me. 1901) (abortion)

State v. Dore, 119 A. 119 (Me. 1922) (manslaughter by illegal abortion)

State v. Rudman, 136 A. 817 (Me. 1927) (abortion) (physician defendant)

State v. Alquist, 34 A.2d 21 (Me. 1943) (abortion)

Maryland

Hays v. State, 40 Md. 633 (1874) (abortion)

Lamb v. State, 7 A. 399 (Md. 1886) (abortion)

Jones v. State, 17 A.89 (Md. 1889) (abortion)

Worthington v. State, 48 A. 355 (Md. 1901) (manslaughter by illegal abortion) (physician defendant)

Hawkins v. State, 57 A. 27 (Md. 1904) (manslaughter by illegal abortion) (physician defendant)

Damm v. State, 97 A. 645 (Md. 1916) (manslaughter by illegal abortion) (physician defendant)

Conaway v. State, 118 A. 135 (Md. 1922) (abortion)

Wilson v. State, 26 A.2d 770 (Md. 1942) (abortion) (physician defendant)

Meyerson v. State, 28 A.2d 833 (Md. 1942) (abortion)

Adams v. State, 88 A.2d 556 (Md. 1952) (abortion) (one physician defendant, one nurse defendant and a third defendant)

Auchincloss v. State, 89 A.2d 605 (Md. 1952) (abortion)

Hutson v. State, 96 A.2d 593 (Md. 1953) (abortion)

Basoff v. State, 119 A.2d 917 (Md. 1956) (abortion)

Humphries v. State, 149 A.2d 23 (Md. 1959) (abortion)

Roeder v. State, 244 A.2d 895 (Md. Ct. Spec. App. 1968) (abortion)

Vios v. State, 246 A.2d 313 (Md. Ct. Spec. App. 1968) (abortion)

Price v. State, 254 A.2d 219 (Md. Ct. Spec. App. 1969) (abortion)

Lashley v. State, 268 A.2d 502 (Md. Ct. Spec. App. 1970) (abortion)

Vuitch v. State, 271 A.2d 371 (Md. Ct. Spec. App. 1970) (abortion) (physician defendant)

Massachusetts

Commonwealth v. Morrison, 82 Mass. 224 (1860) (abortion)

Commonwealth v. Sholes, 95 Mass. 554 (1866) (abortion)

Commonwealth v. Felch, 132 Mass. 22 (1882) (abortion)

Commonwealth v. Barros, 56 N.E. 830 (Mass. 1900) (abortion)

Commonwealth v. Hartford, 79 N.E. 784 (Mass. 1907) (abortion)

Commonwealth v. Turner, 112 N.E. 864 (Mass. 1916) (abortion) (physician defendant)

Commonwealth v. Cantor, 149 N.E. 205 (Mass. 1925) (abortion)

Commonwealth v. Leger, 162 N.E. 337 (Mass. 1928) (abortion) (physician defendant)

Commonwealth v. Morris, 162 N.E 362 (Mass. 1928) (abortion)

Commonwealth v. Hamel, 163 N.E. 168 (Mass. 1928) (abortion)

Commonwealth v. Hebert, 163 N.E. 189 (Mass. 1928) (abortion) (physician defendant)

Commonwealth v. Donoghue, 165 N.E. 413 (Mass. 1929) (abortion)

Commonwealth v. Polian, 193 N.E. 68 (Mass. 1934) (abortion) (pharmacist defendant)

Commonwealth v. Wood, 19 N.E.2d 320 (Mass. 1938) (abortion)

Commonwealth v.Dawn, 19 N.E.2d 315 (Mass. 1939) (abortion) (nurse defendant)

Commonwealth v. Wheeler, 53 N.E.2d 4 (Mass. 1944) (abortion) (physician defendant)

Commonwealth v. Hoff, 53 N.E.2d 680 (Mass. 1944) (abortion) (physician defendant)

Commonwealth v. Hersey, 85 N.E.2d 447 (Mass. 1949) (abortion) (physician defendant)

Commonwealth v. Viera, 109 N.E.2d 171 (Mass. 1952) (abortion)

Commonwealth v. Aronson, 115 N.E.2d 362 (Mass. 1952) (abortion) (physician defendant)

Commonwealth v. Goldenberg, 155 N.E.2d 187 (Mass. 1959) (abortion)

Commonwealth v. Brunelle, 171 N.E.2d 850 (Mass. 1961) (abortion) (physician defendant)

Commonwealth v. Brunelle, 277 N.E.2d 826 (Mass. 1972) (abortion) (physician defendant)

Commonwealth v. Schaflander, 279 N.E.2d 670 (Mass. 1972) (abortion)

Commonwealth v. Kudish, 289 N.E.2d 856 (Mass. 1972) (abortion) (physician defendant)

Michigan

People v. McDowell, 30 N.W. 68 (Mich, 1886) (manslaughter by illegal abortion)

People v. Hodge, 104 N.W. 599 (Mich, 1905) (manslaughter by illegal abortion)

People v. Atwood, 154 N.W. 112 (Mich, 1915) (manslaughter by illegal abortion)

People v. Fritch, 178 N.W. 59 (Mich. 1920) (manslaughter by illegal abortion) (physician defendant)

People v. LaPanne, 237 N.W. 38 (Mich. 1931) (manslaughter by illegal abortion)

People v. Southwick, 261 N.W. 320 (Mich, 1935) (manslaughter by illegal abortion) (physician defendant)

People v. Bradfield, 1 N.W.2d 550 (Mich, 1942) (manslaughter by illegal abortion) (physician defendant)

People v. Robertson, 3 N.W.2d 26 (Mich. 1942) (manslaughter by illegal abortion)

People v. Lewis, 8 N.W.2d 917 (Mich. 1943) (manslaughter by illegal abortion)

People v. Heibel, 9 N.W.2d 826 (Mich. 1943) (abortion)

People v. Jones, 13 N.W.2d 201 (Mich. 1944) (abortion)

People v. Sinclair, 42 N.W.2d 786 (Mich, 1950) (manslaughter by illegal abortion)

People v. Holcomb, 103 N.W.2d 457 (Mich, 1960) (manslaughter by illegal abortion) (physician defendant)

People v. Knox, 111 N.W.2d 828 (Mich. 1961) (abortion) (physician defendant)

People v. Wellman, 149 N.W.2d 908 (Mich. Ct. App. 1967) (abortion) (physician defendant)

People v. Thomas, 152 N.W.2d 166 (Mich. Ct. App. 1967) (abortion) (physician defendant)

People v. Wolke, 159 N.W.2d 882 (Mich. Ct. App. 1968) (abortion)

People v. Hungate, 183 N.W.2d 634 (Mich. 1970) (manslaughter by illegal abortion)

People v. Bartello, 192 N.W.2d 664 (Mich. Ct. App. 1971) (abortion)

People v. Bricker, 201 N.W.2d 647 (Mich. Ct. App. 1972) (abortion), *aff'd*, 208 N.W.2d 172 (Mich, 1973)

Minnesota

State v. Owens, 22 Minn. 238 (1875) (abortion)

State v. Pearce, 57 N.W. 652 (Minn. 1893) (manslaughter by illegal abortion) (physician defendant)

State v. Bly, 108 N.W. 833 (Minn. 1906) (abortion) (physician defendant)

State v. Mueller, 141 N.W. 1113 (Minn. 1913) (manslaughter by illegal abortion) (physician defendant)

State v. Hunter, 154 N.W. 1083 (Minn. 1915) (manslaughter by illegal abortion) (physician defendant)

State v. Newell, 159 N.W. 829 (Minn. 1916) (manslaughter by illegal abortion)

State v. Hatch, 164 N.W. 1017 (Minn. 1917) (manslaughter by illegal abortion) (physician defendant)

State v. Baker, 200 N.W. 815 (Minn. 1924) (manslaughter by illegal abortion)

State v. Doty, 208 N.W. 760 (Minn.1926) (manslaughter by illegal abortion)

State v. French, 210 N.W. 45 (Minn. 1926) (manslaughter by illegal abortion) (physician defendant)

State v. Hecklin, 225 N.W. 925 (Minn. 1929) (abortion)

State v. Zabrocki, 260 N.W. 507 (Minn. 1935) (manslaughter by illegal abortion)

State v. Lemke, 290 N.W. 307 (Minn. 1940) (manslaughter by illegal abortion) (physician defendant)

State v. Brown, 296 N.W. 582 (Minn. 1941) (manslaughter by illegal abortion)

State v. Tennyson, 2 N.W.2d 833 (Minn. 1942) (abortion)

Mississippi

Johnson v. State, 23 So.2d 499 (Miss. 1945) (manslaughter by illegal abortion)

Lackey v. State, 60 So.2d 503 (Miss. 1952) (manslaughter by illegal abortion)

Phillips v. State, 123 So.2d 449 (Miss. 1960) (abortion)

Spears v. State, 257 So.2d 876 (Miss. 1972) (abortion)

Missouri

State v. Fitzporter, 16 Mo. App. 282 (1884) (abortion)

State v. Fitzporter, 17 Mo. App. 271 (1885) (abortion)

State v. Morehead, 17 Mo. App. 328 (1885) (abortion) (physician defendant)

State v. Edmonson, 33 S.W. 17 (Mo. 1895) (manslaughter by illegal abortion)

State v. McLeod, 37 S.W. 828 (Mo. 1896) (manslaughter by illegal abortion)

State v. Dean, 85 Mo. App. 473 (1900) (abortion)

State v. Hogan, 100 S.W. 528 (Mo. Ct. App. 1907) (abortion)

State v. Casto, 132 S.W. 1115 (Mo. 1910) (abortion)

State v. Gow, 138 S.W. 648 (Mo. 1911) (abortion)

State v. Aitken, 144 S.W. 499 (Mo. 1912) (manslaughter by illegal abortion)

State v. Bickel, 177 S.W. 310 (Mo. 1915 (manslaughter by illegal abortion)

State v. Carryer, 180 S.W. 850 (Mo. 1915) (abortion)

State v. Hawkins, 210 S.W. 4 (Mo. 1919) (abortion) (physician defendant)

State v. Steele, 217 S.W. 80 (Mo. 1919) (abortion)

State v. Johnson, 246 S.W. 894 (Mo. 1922) (abortion) (physician defendant)

State v. Anderson, 250 S.W 68 (Mo. 1923) (manslaughter by illegal abortion) (physician defendant)

State v. Harmon, 278 S.W. 733 (Mo. 1925) (abortion) (physician defendant)

State v. Anderson, 34 S.W.2d 25 (Mo. 1930) (manslaughter by illegal abortion) (physician defendant)

State v. Futrell, 46 S.W.2d 588 (Mo. 1931) (abortion) (physician defendant)

State v. Ryan, 50 S.W.2d 999 (Mo. 1932) (manslaughter by illegal abortion) (physician defendant)

State v. Hyatt, 71 S.W.2d 711 (Mo. 1934) (manslaughter by illegal abortion) (physician defendant)

State v. Baker, 143 S.W.2d 244 (Mo. 1940) (abortion)

State v. Duppree, 147 S.W.2d 419 (Mo. 1940) (manslaughter by illegal abortion)

State v. Gunther, 169 S.W.2d 404 (Mo. 1943) (manslaughter by illegal abortion)

State v. Fitzgerald, 174 S.W.2d 211 (Mo. 1943) (abortion) (chiropractor defendant)

State v. Seddon, 208 S.W.2d 212 (Mo. 1948) (abortion)

State v. Miller, 261 S.W.2d 103 (Mo. 1953) (abortion)

State v. Hacker, 291 S.W.2d 155 (Mo. 1956) (abortion)

State v. Stillman 301 S.W.2d 886 (Mo. 1957) (abortion)

State v. Stillman, 310 S.W.2d 830 (Mo. 1957) (abortion)

State v. Scown, 312 S.W.2d 782 (Mo. 1958) (abortion)

State v. Werbin, 345 S.W.2d 103 (Mo. 1961) (manslaughter by illegal abortion) (physician defendant)

State v. Siekermann, 367 S.W.2d 643 (Mo. 1963) (abortion)

State v. Robinson, 420 S.W.2d 272 (Mo. 1967) (abortion) (physician defendant)

State v. Steele, 445 S.W.2d 636 (Mo. 1969) (abortion)

State v. Mucie, 448 S.W.2d 879 (Mo. 1970) (manslaughter by illegal abortion) (physician defendant)

Montana

No reported cases affirming a conviction for abortion or an abortion related offense

Nebraska

Dixon v. State, 64 N.W. 861 (Neb. 1895) (abortion)

Edwards v. State, 112 N.W. (Neb. 1907) (homicide by illegal abortion)

Johnson v. State, 129 N.W. 281 (Neb. 1911) (abortion)

Fields v. State, 185 N.W. 400 (Neb. 1921) (abortion) (physician defendant)

Matthews v. State, 197 N.W. 602 (Neb. 1924) (abortion) (physician defendant)

Edwards v. State, 204 N.W. 780 (Neb. 1925) (abortion and homicide by illegal abortion) (physician defendant)

Rice v. State, 234 N.W. 566 (Neb. 1931) (abortion)

Piercey v. State, 293 N.W. 99 (Neb. 1940) (abortion) (physician defendant)

Nevada

State v. Elges, 251 P.2d 590 (Nev. 1953) (abortion) (physician defendant)

Wyatt v. State, 367 P.2d 104 (Nev. 1961) (abortion) (physician defendant)

Adams v. State, 407 P.2d 169 (Nev. 1965) (abortion)

New Hampshire

State v. Wood, 53 N.H. 484 (1873) (murder by illegal abortion) (physician defendant)

New Jersey

State v. Murphy, 27 N.J.L. 112 (N.J. 1858) (abortion)

State v. Hyer, 39 N.J.L. 598 (N.J. 1877) (abortion)

Engle v. State, 13 A. 604 (N.J. 1887) (abortion)

State v. Meyer, 47 A. 486 (N.J. 1900) (abortion) (physician defendant)

State v. Barnes, 68 A. 145 (N.J. 1907) (abortion)

State v. Fletcher, 72 A. 33 (N.J. (1908) (abortion) (physician defendant)

State v. Wilson, 75 A. 776 (N.J. 1909) (abortion) (physician defendant)

State v. Loomis, 97 A. 896 (N.J. 1916) (abortion) (physician defendant)

State v. Riccio, 100 A. 187 (N.. 1917) (abortion)

State v. Fletcher, 101 A. 181 (N.J. 1917) (abortion)

State v. Kaskevich, 118 A. 701 (N.J. 1922) (abortion) (physician defendant)

State v. Bricker, 118 A. 747 (N.J. 1922) (abortion) (physician defendant)

State v. Bricker, 123 A. 297 (N.J. 1924) (abortion) (physician defendant)

State v. Gardkowski, 140 A. 249 (N.J. 1927) (abortion)

State v. Edwards, 152 A. 452 (N.J. 1930) (abortion)

State v. Corson, 157 A. 103 (N.J. 1931) (abortion)

State v. Parks, 189 A. 384 (N.J. 1936) (abortion) (physician defendant)

State v. McFadden, 24 A.2d 520 (N.J. 1942) (abortion)

State v. Weiss, 31 A.2d 848 (N.J. 1943) (abortion)

State v. Jaworksi, 34 A.2d 412 (N.J. 1943) (abortion)

State v. Lisena, 34 A.2d 737 (N.J. 1943) (abortion)

State v. Sturchio, 36 A.2d 301 (N.J. 1944) (abortion) (physician defendant)

State v. King, 44 A.2d 901 (N.J. 1945) (abortion)

State v. Dillingham, 46 A.2d 813 (N.J. 1946) (abortion)

State v. Boyd, 57 A.2d 521 (N.J. 1947) (abortion)

State v. Brandenburg, 58 A.2d 709 (N.J. 1947) (abortion) (physician defendant)

State v. Ellrich, 89 A.2d 685 (N.J. 1952) (abortion) (physician defendant)

State v. Pometti, 97 A.2d 399 (N.J. 1953) (abortion)

State v. Novak, 125 A.2d 521 (N.J. 1956) (abortion)

State v. Sudol, 129 A.2d 29 (N.J. Super. 1957) (abortion)

State v. Colmer, 132 A.2d 325 (N.J. Super. 1957) (abortion) (physician defendant)

State v. Doyle, 200 A.2d 606 ((N.J. 1964) (abortion) (physician defendant)

State v. Moretti, 244 A.2d 499 (N.J. 1968) (abortion) (physician defendant)

State v. Raymond, 273 A.2d 399 (N.J. Super. 1971) (abortion)

State v. Haren, 307 A.2d 644 (N.J. Super. 1973) (abortion)

State v. Norfleet, 337 A.2d 609 (N.J. 1975) (abortion)

New Mexico

State v. Grissom, 298 P. 666 (N.M. 1930) (abortion) (dentist defendant)

State v. Lewis, 12 P.2d 849 (N.M. 1932) (abortion) (physician defendant)

State v. Morris, 365 P.2d 668 (N.M. 1964) (abortion)

State v. Gutierrez, 408 P.2d 503 (N.M. 1965) (abortion)

New York

Lohman v. People, 1 N.Y. 379 (1848) (abortion)

Dunn v. People, 29 N.Y. 523 (1864) (abortion)

Mongeon v. People, 55 N.Y. 613 (1874) (manslaughter by illegal abortion)

Weed v. People, 56 N.Y. 628 (1874) (abortion)

Hawker v. People, 75 N.Y. 487 (1878) (abortion)

Eckhardt v. People, 83 N.Y. 462 (1881) (abortion)

People v. Vedder, 98 N.Y. 630 (1885) (abortion)

People v. Bliven, 19 N.E. 638 (N.Y. 1889) (abortion)

People v. Conrad, 74 N.E. 1122 (N.Y. 1905) (abortion)

People v. Weick, 107 N.Y.S. 968 (N.Y. App. Div. 1908) (manslaughter by illegal abortion)

People v. Wagar, 84 N.E. 1117 (N.Y. 1908) (abortion)

People v. Blinn, 90 N.E. 1163 (N.Y. 1909) (abortion)

People v. Curtis, 136 N.Y.S.2d 582 (N.Y. App. Div. 1912) (abortion)

People v. Papp, 150 N.Y.S. 1102 (N.Y. App. Div. 1914) (abortion)

People v. Miller, 129 N.E. 910 (N.Y. 1920) (abortion)

People v. Hammer, 134 N.E. 573 (1921) (manslaughter by illegal abortion) (physician defendant)

People v. Williams, 23 N.Y.S.2d 487 (N.Y. App. Div. 1940) (manslaughter by illegal abortion, abortion)

People v. Blank, 29 N.E.2d 73 (N.Y. 1940) (abortion) (physician defendants)

People v. Nisonoff, 45 N.Y.S.2d 854 (N.Y. App. Div. 1944) (manslaughter by illegal abortion) (physician defendants)

People v. Leventhal, 66 N.E.2d 126 (N.Y. 1946) (abortion)

People v. Hodsgon, 74 N.E.2d 482 (N.Y. 1947) (abortion)

People v. Singer, 89 N.E.2d 710 (N.Y. 1949) (manslaughter by illegal abortion, abortion) (physician defendant)

People v. Sorge, 94 N.Y.S.2d 267 (N.Y. App. Div. 1950) (abortion)

People v. Davis, 105 N.Y.S.2d 986 (N.Y. App. Div. 1951) (abortion)

People v. Maschietto, 130 N.Y.S.2d 828 (N.Y. App. Div. 1954) (abortion)

People v. Kempf, 48 N.Y.S.2d 319 (N.Y. App. Div. 1956) (abortion)

People v. Munoz, 202 N.Y.S.2d 742 (N.Y. App. Div. 1960) (manslaughter by illegal abortion)

People v. Kelly, 204 N.Y.S.2d 127 (N.Y. App. Div. 1960) (abortion)

People v. Hovnanian, 228 N.Y.S. 771 (N.Y. App. Div. 1962) (manslaughter by illegal abortion)

People v. Settini, 191 N.E.2d 678 (N.Y. 1963) (abortion)

People v. Halio, 195 N.E.2d 895 (N.Y. 1963) (abortion)

People v. Davis, 222 N.E.2d 734 (N.Y. 1966) (abortion)

People v. Mendez, 268 N.E.2d 778 (N.Y. 1971) (abortion)

People v. Perel, 315 N.E.2d 452 (N.Y. 1974) (abortion)

North Carolina

State v. Slagle, 83 N.C. 630 (1880) (abortion)

State v. Mills, 21 S.E. 106 (N.C. 1895) (murder by illegal abortion)

State v. Crews, 38 S.E. 293 (N.C. 1901) (abortion)

State v. Shaft, 81 S.E. 932 (N.C. 1914) (abortion)

State v. Summers, 82 S.E. 328 (N.C. 1917) (manslaughter by illegal abortion) (physician defendant)

State v. Brady, 99 S.E. 7 (N.C. 1919) (abortion)

State v. Powell, 106 S.E. 133 (N.C. 1921) (abortion)

State v. Martin, 109 S.E. 74 (N.C. 1921) (abortion)

State v. Russell, 117 S.E. 807 (N.C. 1923) (abortion)

State v. Gurkhas, 143 S.E. 208 (N.C. 1928) (abortion)

State v. Layton, 169 S.E. 650 (N.C. 1933) (murder by illegal abortion)

State v. Evans, 190 S.E. 724 (N.C. 1937) (abortion)

State v. Baker, 193 S.E. 22 (N.C. 1937) (abortion)

State v. Thompson, 4 S.E.2d 615 (N.C. 1939) (abortion)

State v. Manning, 33 S.E.2d 239 (N.C. 1945) (abortion)

State v. Gardner, 40 S.E.2d 415 (N.C. 1946) (murder by illegal abortion) (physician defendant)

State v. Farley, 95 S.E.2d 448 (N.C. 1956) (abortion)

State v. Lee, 103 S.E.2d 295 (N.C. 1958) (abortion) (physician defendant)

State v. Hoover, 113 S.E.2d 281 (N.C. 1960) (abortion)

State v. Stroud, 119 S.E.2d 907 (N.C. 1961) (manslaughter by illegal abortion)

State v. Mitchner, 124 S.E.2d 831 (N.C. 1962) (manslaughter by illegal abortion)

State v. Brooks, 148 S.E.2d 263 (N.C. 1966) (abortion)

State v. Coleman, 193 S.E.2d 395 (N.C. Ct. App. 1972) (abortion)

North Dakota

State v. Longstreth, 121 N.W. 1114 (N.D. 1909) (abortion) (physician defendant)

State v. Moeller, 138 N.W. 981 (N.D. 1912) (murder by illegal abortion)

State v. Reilly, 141 N.W. 720 (N.D. 1913) (murder by illegal abortion) (physician defendant)

State v. Shortridge, 211 N.W. 336 (N.D. 1926) (murder by illegal abortion) (physician defendant)

State v. Dimmick, 296 N.W. 146 (N.D. 1941) (abortion) (physician defendant)

Ohio

Wilson v. State, 2 Ohio St. 319 (1853) (abortion)

Tabler v. State, 34 Ohio St. 127 (1877) (abortion)

Waite v. State, 4 Ohio App. 451 (1915) (abortion)

Bridge v. State, 1912 Ohio Misc. LEXIS 302, *aff'd*, 87 Ohio St. 464 (1912) (abortion)

State v. Lehr, 119 N.E. 730 (Ohio 1918) (abortion)

Schneider v. State, 1922 Ohio Misc. LEXIS 203 (Ohio Ct. App.) (abortion)

Schunn v. State, 1923 Ohio Misc. LEXIS 1559 (Ohio Ct. App.) (abortion)

Gaskins v. State, 160 N.E. 500 (Ohio Ct. App. 1927) (abortion) (physician defendant)

Clyne v. State, 174 N.E. 767 (Ohio 1931) (abortion)

State v. Jones, 70 N.E.2d 913 (Ohio Ct. App. 1946) (abortion) (physician defendant)

State v. Coran, 94 N.E.2d 562 (Ohio Ct. App. 1948) (abortion)

State v. Andlauer, 131 N.E.2d 672 (Ohio Ct. App. 1955) (abortion) (physician defendant)

State v. Brown 137 N.E.2d 609 (Ohio Ct. App. 1955) (abortion)

State v. Allgood, 171 N.E.2d 186 (Ohio 1959) (abortion) (physician defendant)

Oklahoma

Greenwood v. State, 105 P. 371 (Okla. Crim. App. 1909) (abortion)

Chandler v. State, 105 P. 375 (Okla. Crim. App. 1909) (abortion)

Copus v. State, 224 P. 364 (Okla. Crim. App. 1924) (manslaughter by illegal abortion) (dentist defendant)

Davis v. State, 234 P. 787 (Okla. Crim. App. 1925) (murder by illegal abortion) (physician defendant)

Wilson v. State, 252 P. 1106 (Okla. Crim. App. 1927) (abortion) (physician defendant)

Adams v. State, 21 P.2d 1075 (Okla. Crim. App. 1933) (abortion)

Thacker v. State, 26 P.2d 770 (Okla. Crim. App. 1933) (murder by illegal abortion) (physician defendant)

Smith v. State, 175 P.2d 348 (Okla. Crim. App. 1946) (manslaughter by illegal abortion)

Cahill v. State, 178 P.2d 657 (Okla. Crim. App. 1947) (abortion)

Oregon

State v. Glass, 5 Or. 73 (1873) (manslaughter by illegal abortion) (physician defendant)

State v. Atwood, 104 P. 195 (Ore. 1909) (abortion)

State v. Ausplund, 167 P. 1019 (Ore. 1917) (manslaughter by illegal abortion) (physician defendant)

State v. Bertschinger, 177 P. 63 (Ore. 1919) (manslaughter by illegal abortion)

State v. Jeannet, 192 P.2d 983 (Ore. 1948) (manslaughter by illegal abortion) (physician defendant)

State v. Elliott, 289 P.2d 1075 (Ore. 1955) (manslaughter by illegal abortion) (chiropractor defendant)

State v. Buck, 398 P.2d 171 (Or. 1965) (manslaughter by illegal abortion) (physician defendant)

State v. Barnett, 433 P.2d 1019 (Or. 1967) (manslaughter by illegal abortion)

State v. Beeson, 434 P.2d 460 (Ore. 1967) (manslaughter by illegal abortion)

State v. Barnett, 437 P.2d 821 (Or. 1967) (manslaughter of unborn child by illegal abortion)

State v. Sinclair, 454 P.2d 858 (Or. 1969) (manslaughter by illegal abortion)

State v. Schulman, 485 P.2d 1252 (Or. Ct. App. 1971) (abortion)

Pennsylvania

Mills v. Commonwealth, 13 Pa. 634 (1850) (abortion)

Cox v. Commonwealth, 17 A. 227 (Pa. 1889) (abortion) (physician defendant)

Commonwealth v. Rosenberry, 3 Pa. Super 408 (1897) (abortion)

Commonwealth v. Page, 6 Pa. Super. 220 (1897) (abortion)

Commonwealth v. Mitchell, 6 Pa. Super 369 (1898) (abortion) (physician defendant)

Commonwealth v. Keene, 7 Pa. Super 293 (1898) (abortion) (physician defendant)

Commonwealth v. Winkelman, 12 Pa. Super. 497 (1900) (homicide by illegal abortion)

Commonwealth v. Haun, 27 Pa. Super 33 (1904) (abortion)

Commonwealth v. Penrose, 27 Pa. Super 101 (1905) (abortion) (physician defendant)

Commonwealth v. Bartholomew 35 Pa. Super. 114 (1907) (abortion)

Commonwealth v. Weaver, 61 Pa. Super. 571 (1915) (abortion)

Commonwealth v. Kline, 66 Pa. Super. 285 (1917) (abortion) (physician defendant)

Commonwealth v. Bricker, 74 Pa. Super. 234 (1920) (abortion) (defendant physician)

Commonwealth v. Longwell, 79 Pa. Super 68 (1922) (abortion)

Commonwealth v. Heffelfinger, 82 Pa. Super. 351 (1923) (abortion)

Commonwealth v. Thomas, 94 Pa. Super 353 (1928) (abortion)

Commonwealth v. Kelsea, 157 A. 42 (Pa. Super. Ct. 1931) (abortion) (physician defendant)

Commonwealth v. Felgoise, 194 A. 751 (Pa. Super. Ct. 1937) (abortion) (physician defendant)

Commonwealth v. Trombetta, 200 A. 107 (Pa. Super. 1938) (abortion)

Commonwealth v. Weigand, 5 A.2d 385 (Pa. Super. Ct. 1939) (abortion)

Commonwealth v. Meyers, 22 A.2d 81 (Pa. Super Ct. 1941) (abortion)

Commonwealth v. Kazmierowski, 24 A.2d 653 (Pa. Super. Ct. 1942) (abortion) (physician defendant)

Commonwealth v. Spanos, 34 A.2d 902 (Pa. Super. Ct. 1943) (abortion) (physician defendant)

Commonwealth v. Thomas, 49 A.2d 413 (Pa. Super. Ct. 1946) (abortion) (physician defendant)

Commonwealth v. Campbell, 174 A.2d 324 (Pa. Super. Ct. 1961) (abortion) (physician defendant)

Commonwealth v. Fisher, 203 A.2d 364 (Pa. Super. Ct. 1964) (abortion)

Commonwealth v. Slomanson, 214 A.2d 519 (Pa. Super. Ct. 1965) (abortion)

Commonwealth v. Ross, 241 A.2d 353 (Pa. Super Ct. 1968) (abortion)

Rhode Island

State v. Sousa, 110 A. 603 (R.I. 1920) (abortion)

State v. Durkee, 26 A.2d 604 (R.I. 1942) (abortion)

State v. Lorenzo, 48 A.2d 407 (R.I. 1946) (abortion) (chiropractor defendant)

State v. Lee, 78 A.2d 793 (R.I. 1951) (abortion)

South Carolina

State v. Morrow, 18 S.E. 853 (S.C. 1893) (abortion)

State v. Sharpe, 135 S.E.2d 635 (S.C. 1926) (abortion)

State v. Parsons, 172 S.E. 424 (S.C. 1934) (abortion)

State v. Evans, 25 S.E.2d 492 (S.C. 1943) (abortion)

State v. Steadman, 59 S.E.2d 168 (S.C. 1950) (abortion)

State v. Wells, 153 S.E.2d 904 (S.C. 1967) (abortion)

South Dakota

State v. Hanson, 220 N.W. 518 (S.D. 1928) (abortion)

Tennessee

Miller v. State, 225 S.W.2d 62 (Tenn. 1949) (abortion)

Suggs v. State, 258 S.W.2d 747 (Tenn. 1953) (abortion)

Leek v. State, 392 S.W.2d 456 (Tenn. 1965) (abortion)

Williams v. State, 403 S.W.2d 319 (Tenn. 1966) (abortion)

Webster v. State, 425 S.W.2d 799 (Tenn. Ct. Crim App. 1967) (abortion)

Houser v. State, 472 S.W.2d 747 (Tenn. Ct. Crim. App. 1971) (abortion)

Texas

Willingham v. State, 25 S.W. 424 (Tex. Crim. App. 1894) (abortion)

Cave v. State, 26 S.W. 503 (1894) (abortion)

Moore v. State, 40 S.W. 287 (Tex. Crim. App. 1897) (abortion)

Hunter v. State, 41 S.W. 602 (Tex. Crim. App. 1897) (abortion)

Reum v. State, 90 S.W. 1109 (Tex. Crim. App. 1905) (abortion) (physician defendant)

Link v. State, 164 S.W. 987 (Tex. Crim. App. 1914) (abortion) (physician defendant)

Shaw v. State, 165 S.W. 930 (Tex. Crim. App. 1914) (abortion)

Fondren v. State, 169 S.W. 411 (Tex. Crim. App. 1914) (abortion)

Gray v. State, 178 S.W. 337 (Tex. Crim. App. 1915) (abortion)

Hunter v. State, 196 S.W. 820 (Tex. Crim. App. 1917) (abortion)

Hammett v. State, 209 S.W. 661 (Tex. Crim. App. 1919) (abortion)

Earnest v. State, 224 S.W. 777 (Tex. Crim. App. 1920) (abortion) (physician defendant)

Jordan v. State, 92 S.W.2d 1024 (Tex. Crim. App. 1936) (abortion)

Bristow v. State, 128 S.W.2d 818 (Tex. Crim. App. 1939) (abortion)

Pearson v. State, 165 S.W.2d 725 (Tex. Crim. App. 1942) (abortion)

Housman v. State, 230 S.W.2d 541 (Tex. Crim. App. 1950) (abortion)

Jarquin v. State, 232 S.W.2d 736 (Tex. Crim. App. 1950) (abortion)

Nelson v. State, 257 S.W.2d 306 (Tex. Crim. App. 1952) (abortion)

Welch v. State, 264 S.W.2d 100 (Tex. Crim. App. 1953) (abortion)

Mayberry v. State, 271 S.W.2d 635 (Tex. Crim. App. 1954) (abortion)

Cortez v. State, 275 S.W.2d 123 (Tex. Crim. App. 1954) (abortion) (physician defendant)

Owens v. State, 283 S.W.2d 749 (Tex. Crim. App. 1955) (abortion)

Redman v. State, 287 S.W.2d 676 (Tex. Crim. App. 1955) (murder by illegal abortion)

Romero . State, 308 S.W.2d 49 (Tex. Crim. App. 1957) (abortion)

Parnell v. State, 312 S.W.2d 506 (Tex. Crim. App. 1958) (abortion)

Veevers v. State, 354 S.W.2d 161 (Tex. Crim. App. 1962) (abortion)

Fletcher v. State, 362 S.W.2d 845 (Tex. Crim. App. 1962) (abortion)

Thompson v. State, 493 S.W.2d 913 (Tex. Crim. App. 1971) (abortion) (physician defendant), *vacated and remanded*, 410 U.S. 950 (1973)

Utah

State v. McCoy, 49 P. 420 (Utah 1897) (abortion) (physician defendant)

Vermont

State v. Howard, 32 Vt. 380 (1859) (abortion) (physician defendant)

State v. Ryder, 68 A. 652 (Vt. 1907) (abortion) (physician defendant)

State v. Bolton, 102 A. 489 (Vt. 1917) (abortion) (physician defendant)

State v. Marini, 170 A. 110 (Vt. 1934) (abortion) (physician defendant)

Virginia

Coffman v. Commonwealth, 50 S.E.2d 431 (Va. 1948) (abortion)

Anderson v. Commonwealth, 58 S.E.2d 72 (Va. 1950) (abortion) (physician defendant)

Mendoza v. Commonwealth, 103 S.E.2d 1 (Va. 1958) (abortion)

Russo v. Commonwealth, 148 S.E.2d 820 (Va. 1966) (abortion) (physician defendant)

Washington

State v. Power, 63 P. 1112 (Wash. 1901) (manslaughter by illegal abortion) (physician defendant)

State v. Stapp, 118 P. 337 (Wash. 1911) (abortion) (physician defendant)

State v. Macleod, 138 P. 649 (Wash. 1914) (manslaughter by illegal abortion) (physician defendant)

State v. Gaul, 152 P. 1029 (Wash. 1915) (abortion)

State v. Russell, 156 P. 565 (Wash. 1916) (abortion)

State v. Powers, 283 P. 439 (Wash. 1929) (abortion) (physician defendant)

State v. Bengston, 292 P. 1107 (Wash. 1930) (abortion)

State v. Martin, 34 P.2d 914 (Wash. 1934) (abortion, manslaughter by illegal abortion) (physician defendant)

State v. Cox, 84 P2d 357 (Wash. 1938) (abortion) (physician defendant)

State v. De Gaston, 104 P.2d 756 (Wash. 1940) (abortion)

State v. Payne, 171 P.2d 227 (Wash. 1946) (manslaughter by illegal abortion) (physician defendant)

State v. Hart, 175 P.2d 944 (Wash. 1946) (manslaughter by illegal abortion) (physician defendant)

State v. Bates, 324 P.2d 810 (Wash. 1958) (abortion)

State v. Goddard, 351 P.2d 159 (Wash. 1960) (abortion)

State v. Craig, 367 P.2d 617 (Wash. 1961) (abortion)

State v. Craig, 430 P.2d 560 (Wash. 1966) (abortion)

State v. Wright, 444 P.2d 676 (Wash. 1968) (abortion)

State v. Goddard, 447 P.2d 180 (Wash. 1968) (abortion)

West Virginia

State v. Lilly, 35 S.E. 837 (W. Va. 1900) (abortion)

State v. Lewis, 57 S.E.2d 513 (W.Va. 1949) (murder by illegal abortion) (physician defendant)

State v. Evans, 66 S.E.2d 545 (W.Va. 1951) (abortion) (physician defendant)

Wisconsin

State v. Dickinson, 41 Wis. 299 (1877) (manslaughter by illegal abortion)

Hatchard v. State, 48 N.W. 380 (Wis. 1891) (manslaughter by illegal abortion)

State v. Law, 136 N.W. 803 (Wis. 1912) (abortion) (physician defendant)

Rodermund v. State, 168 N.W. 390 (Wis. 1918) (abortion) (physician defendant)

Hunter v. State, 192 N.W. 984 (Wis. 1923) (abortion)

Werner v. State, 206 N.W. 898 (Wis. 1926) (abortion) (physician defendant)

State v. Walters, 225 N.W. 167 (Wis. 1929) (manslaughter by illegal abortion)

Bonich v. State, 232 N.W. 873 (Wis. 1930) (abortion)

Parke v. State, 235 N.W. 775 (Wis. 1931) (abortion) (physician defendant)

State v. Henderson, 274 N.W. 266 (Wis. 1937) (abortion) (physician defendant)

Kraut v. State, 280 N.W. 327 (Wis. 1938) (manslaughter by illegal abortion) (physician defendant)

Schlesak v. State, 287 N.W. 703 (Wis. 1939) (manslaughter by illegal abortion)

State v. Timm, 12 N.W.2d 670 (Wis. 1944) (manslaughter by illegal abortion) (physician defendant)

State v. Ketchum, 56 N.W.2d 531 (Wis. 1952) (murder by illegal abortion)

State v. Cohen, 142 N.W.2d 161 (Wis. 1966) (abortion) (physician defendant)

State v. Harling, 170 N.W.2d 720 (Wis. 1969) (abortion)

Wyoming

No reported cases affirming a conviction for abortion or an abortion related offense.

Table of Cases by State and Decade

State/Decade	1840s	1850s	1860s	1870s	1880s	1890s	1900s	1910s	1920s	1930s	1940s	1950s	1960s	1970s	Totals
Alabama							1	1	1		2			2	7
Alaska															0
Arizona										1	1	1			3
Arkansas							1	2	1	1	1		1	2	9
California							2	11	10	11	20	41	25		120
Colorado				2			3	2	3		7		2	1	20
Connecticut						1	1		3		1		1		7
Delaware													1		1
Florida						1		2			2	2	7	1	15
Georgia							2	1	3	2	1	4	1	2	16
Hawaii											4				4
Idaho							1					1			2
Illinois	1		1	2	1	2	5	3	2	9	7	4	7	2	46
Indiana		1			2		2	3	2	1	1	1	1	1	15
Iowa			1	1	2	2	2		2	1	1	1		1	14
Kansas					1	1	3		1			1		1	8
Kentucky					1						1	4	1	1	8
Louisiana													3	3	6
Maine				1				1		2		1			5
Maryland				1	2		2	1	1		2	5	3	2	19
Massachusetts			2		1		2	1	6	3	3	3	1	3	25
Michigan					1		1	1	1	2	5	1	5	3	20
Minnesota				1		1	1	4	4	1	3				15
Mississippi											1	1	1	1	4
Missouri					3	2	2	7	3	4	5	5	4	1	36
Montana															0
Nebraska						1	1	1	3	1	1				8
Nevada												2	1		3
New Hampshire				1											1
New Jersey		1		1	1		4	3	4	3	9	5	2	3	36

Table (*Continued*)

State/Decade	1840s	1850s	1860s	1870s	1880s	1890s	1900s	1910s	1920s	1930s	1940s	1950s	1960s	1970s	Totals
New Mexico										2			2		4
New York	1		1	3	3		4	2	2		6	4	6	2	34
North Carolina					1	1	1	3	4	4	2	2	4	1	23
North Dakota							1	2	1		1				5
Ohio		1		1				3	3	1	2	3			14
Oklahoma							2		3	2	2				9
Oregon				1			1	2			1	1	5	1	12
Pennsylvania		1			1	4	4	2	4	4	4		4		28
Rhode Island									1		2	1			4
South Carolina						1			1	1	1	1	1		6
South Dakota									1						1
Tennessee											1	1	3	1	6
Texas						4	1	6	1	2	1	10	2	1	28
Utah						1									1
Vermont		1					1	1		1					4
Virginia											1	2	1		4
Washington							1	4	1	3	3	1	5		18
West Virginia							1				1	1			3
Wisconsin				1		1		2	3	5	1	1	2		16
Wyoming															0
Totals	2	5	5	16	20	23	53	71	75	67	107	111	102	36	693

Verbatim

Fetal Pain: What is the Scientific Evidence?

American College of Pediatricians – January 2021

Based on: "The Science Behind Fetal Pain," *The Linacre Quarterly,* August 2020[1]

ABSTRACT

The American College of Pediatricians (ACPeds) maintains that it is unethical to intentionally harm an innocent human being even in the absence of the individual's ability to perceive pain. However, in this paper, ACPeds reviews the laboratory and clinical evidence which indicates that as early as 12 weeks gestation (and possibly earlier) exposure to noxious stimuli negatively affects immature human beings. Because of the resulting acute stress responses and subsequent potential long-term negative effects, the ACPeds holds that avoiding, mitigating, and directly treating fetal, neonatal, and pediatric pain is a medical and ethical obligation.

Introduction

Many have questioned whether pain exists for neurologically immature human beings. Despite how controversial this question may be when raised in the context of elective abortion, there is significant scientific consensus regarding early fetal neuroanatomy and physiology. How pain is defined, however, does not enjoy a similar consensus. Some argue that for pain to be experienced it requires two components, a sensory *and* an emotional/conscious component.[2] If this is true, then human beings' ability to experience pain is limited from conception through the first two years after birth due to neurological immaturity. Others argue against the need for a mature conscious awareness and claim that this same population of children is pain capable. Since the ability of unborn children, infants, and toddlers to communicate the nature of their distress is limited, surrogate markers of pain need to be considered. Such markers are demonstrated in an increasing body of scientific research and include stress and withdrawal responses as well as measurable physiologic changes. Therefore, despite debate over the definition of pain, the medical standard of care currently practiced by pediatricians, neonatologists, and anesthesiologists, is to treat all children, infants, and premature babies (including those still in-utero), as though they are pain capable. While it is clearly unethical to intentionally harm innocent human beings whether or not they cannot perceive pain, that is not this statement's focus. What this paper provides is a brief overview of the scientific evidence behind this standard of care and argues that the 2-component (sensory and emotional) definition of pain is scientifically and ethically untenable.

The science of infant pain

Four decades ago, the medical consensus was that babies do not feel pain. "Until the late 1980's surgical procedures with neonates were mostly performed without anesthesia because of safety concerns and because it was assumed the neonate was not neurologically sophisticated enough to experience pain".[3] But in 1987 *The New England Journal of Medicine (NEJM)* published Drs Anand and Hickey's

landmark paper showing evidence to the contrary.[4] The authors stated, the "focus on pain *perception* [emphasis added] in neonates and confusion over its differentiation from nociceptive activity and the accompanying physiologic responses have obscured the mounting evidence that nociception is important in the biology of the neonate."[4] In other words, concern over whether pain can be perceived by a person who does not yet have a mature, conscious awareness, has obscured actual evidence that an immature person's physiology is changed by pain. Dr. Anand's paper drew upon results from their own work as well as multiple studies in an extensive review of the anatomic requirements for pain perception, the associated neurochemical systems, the physiologic and behavioral changes associated with pain, and the memory of pain in neonates. They concluded, "none of the cited data herein tell us whether neonatal nociceptive activity and associated responses are experienced subjectively…However, the evidence does show that marked nociceptive activity clearly constitutes a physiological and perhaps even a psychological form of stress in premature or full-term neonates."[4] Based on published evidence, they recommended re-evaluating the medical standard of care in favor of providing local and general anesthesia during invasive procedures.[4]

Unequivocally corroborating their previous paper's conclusion, the same group's 1992 *NEJM* publication was arguably even more demonstrative of the effects of pain on newborns and by today's standards, ethically troubling. This was a randomized trial comparing the outcomes of 4 to 10 day old neonates with congenital heart defects, who were eligible for surgical repair.[5] In the operating room, one group received "lighter anesthesia", the other group "deep anesthesia". When the babies' pain was effectively treated their outcomes were considerably improved, including statistically significant differences in intra-operative and post-operative markers of stress (stress hormones, hyperglycemia, lactic acidemia), and fewer postoperative deaths (4 of the 15 neonates died prior to discharge in the light anesthesia group, none of the 30 in the deep anesthesia group died prior to discharge home. This lower rate of mortality "was significantly lower than hospital mortality in other neonates undergoing cardiac surgery with bypass and circulatory arrest during the study period").[5] Because of how compelling these results were, this study could not ethically be repeated. Driven by the data, medical practice in neonatology, pediatrics, and anesthesiology changed; today, babies who are term, premature, or operated on in utero, receive appropriate anesthesia.[1]

The 1992 cardiac surgery study was done with term infants, but with ongoing research and survival at decreasing gestational ages, by 2016, the American Academy of Pediatrics' (AAP) revised policy, *Prevention and Management of Procedural Pain in the Neonate: An Update,* specifically states that even premature babies' pain should be treated, minimized, and/or prevented, "not only because it is ethical but also because repeated painful exposures have the potential for deleterious consequences".[6] The consequences of experiencing pain include: "physiologic instability, altered brain development, and abnormal neurodevelopment, somatosensory, and stress response systems, which can persist into childhood,".[6] Dr. Johnston and Dr. Steven's study is one example of a study that demonstrates a premature baby's capacity to acutely react to noxious stimulation and then retain a procedural memory. The authors evaluated the physiologic responses to painful stimuli in two groups of babies at 32 weeks gestation. They compared newborn 32-week babies, and babies born earlier at 28 weeks gestation whose responses were measured four weeks later when they reached 32 weeks gestation.[7] Measurements included heart rates and oxygen saturation levels before, during, and after a heel stick (commonly used for blood draws in this population), and not only was there an acute response associated with the heel stick in both groups, clear statistical differences between the two groups were also documented. The 4-week-old babies who had experienced this procedure many times previously had even "higher heart rates and lower oxygen saturations than the newborn infants of the same gestational age who had not already had this experience.[7] (figures 1 and 2).

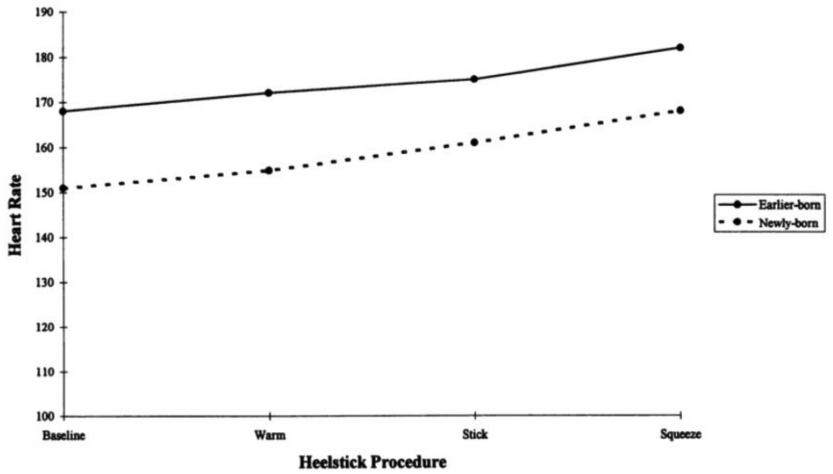

Fig 1. Based on repeated measures analysis of variance, there are differences ($P < .01$) between the two groups and across heel stick procedure.

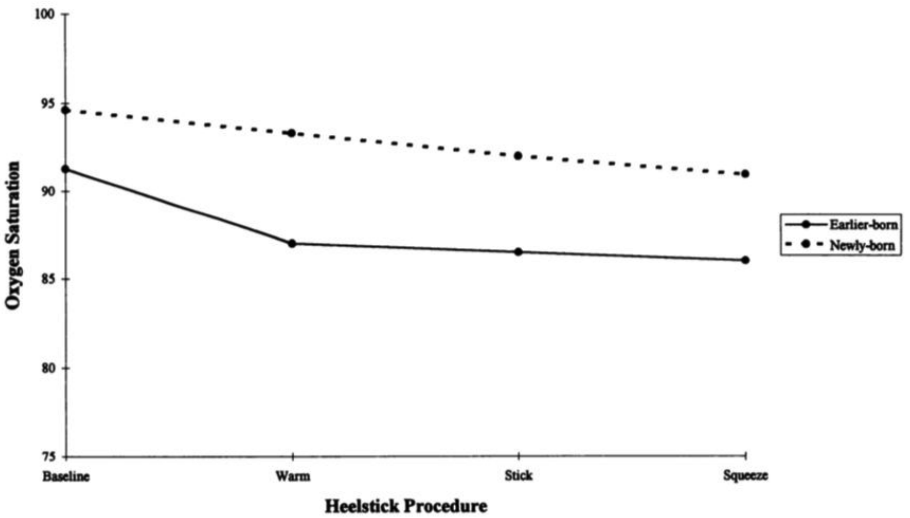

Fig 2. Based on repeated measures analysis of variance, there are differences ($P < .01$) between the two groups and across heel stick procedure.

Premature babies who had already been exposed to painful stimulation showed evidence of being more stressed when the same procedure was repeated than those of the same gestational age who did not have prior experience. The physiologic reactions of premature babies found in this and other studies are why the AAP's recommendations to avoid, mitigate, or treat procedural pain in premature babies is medically and ethically appropriate.[6]

The AAP's 2016 recommendations stated that "nociceptive pathways are active and functional as early

as 25 weeks' gestation,"[6] but premature babies at even younger gestational ages are now routinely cared for in NICUs, and additional data shows that decreasing not only obviously painful procedures but also rethinking how the entire NICU environment affects particularly the youngest and most vulnerable patients, improves their outcomes.[8-9] Two examples of practice changes include: (1) increased use of "kangaroo care" where the premature baby is placed in skin-to-skin contact with either the mother's or father's chest, and (2) cue-based care times, by which instead of checking vital signs every three hours, the staff tries not to interrupt valuable sleep and uses, within reason, the babies' cues that they are awake or in need of being tended to. Multiple centers involved in performance improvement projects associated with the Vermont Oxford Network (an international consortium of more than 1300 hospitals working to improve neonatal care),[10] have made these and other changes to intentionally decrease noxious stimuli from a variety of sources. This has led to the creation of "small baby units" within NICUs, and many hospitals have presented their versions of small baby units as part of their performance improvement results at VON's annual national conference, as well as in formal publications.[9] Again, evidence indicates that our most vulnerable patients are healthier when noxious stimuli is reduced.

Can reactions from premature babies be extrapolated to how they react while in-utero? Because premature babies are now being successfully resuscitated at approximately 22-23 weeks gestation, with a number of cases even a bit lower[11] many premature babies cared for in today's NICUs have predominantly *fetal* physiology. "During the fetal period (9th week after conception to birth), differentiation and growth of the organs formed during the embryonic period occur.".[12,13] Despite premature babies' fetal physiology, their daily witnessed reactions to noxious stimulation, as well as the amelioration of these symptoms with treatment, questions persist as to whether "fetal pain perception can be assessed by reference to the prematurely born infant."[14] This concern is supported by studies that demonstrated a group of chemicals within the intrauterine environment called intrauterine endocrine neuroinhibitors (specifically adenosine, pregnanolone and prostaglandin D2) that may anesthetize the infant.[14-15] This concern was cited by the Royal College of Obstetricians and Gynaecologists in 2010 to rule against fetal pain capability, but their primary evidence is an extrapolation of the chemical environment of fetal sheep.[16] A more recent review of neuroinhibitory studies cited three different publications that found the "neural inhibition effects of both adenosine and PGD2 have been recorded only when they are artificially administered in particular into the brain of test animals and the effect was not analgesic but just sedative."[17] Even if neuroinhibitors do contribute to keeping a fetus predominantly asleep, the chemicals' effect is insufficient to keep them asleep when external stimuli are applied.[17] Another publication noted that "although mild noxious stimuli do not seem to be perceived during such fetal sleep, major tissue injury occurring as a result of fetal trauma or fetal surgical intervention generates behavioral and physiologic arousal."[18] Thus, the make-up of the in-utero chemical milieu may participate in providing the ideal place for immature human beings to develop, but this environment is not equipped to blockade the effects of external painful stimuli.

In-vivo human studies done while still in utero provide additional evidence that noxious stimulation is not blocked. Gitau et al studied the responses of human fetuses who required in-utero blood transfusions. The stress hormone levels when their abdomens were accessed to reach the intrahepatic vein (IHV) for their in-utero blood transfusion, were compared to the stress hormone levels of those who received their transfusion through the placental cord insertion site (PCI), a site that is without innervation.[19] Statistically significant increases in stress hormone levels were documented in the group whose intrahepatic vein was accessed through their abdomen, with "fetal B-endorphin responses apparent from 18 weeks gestation and fetal cortisol responses apparent from 20 weeks gestation…consistent with the maturation of the fetal pituitary before the fetal adrenal [gland]".[19] (See figure 3)

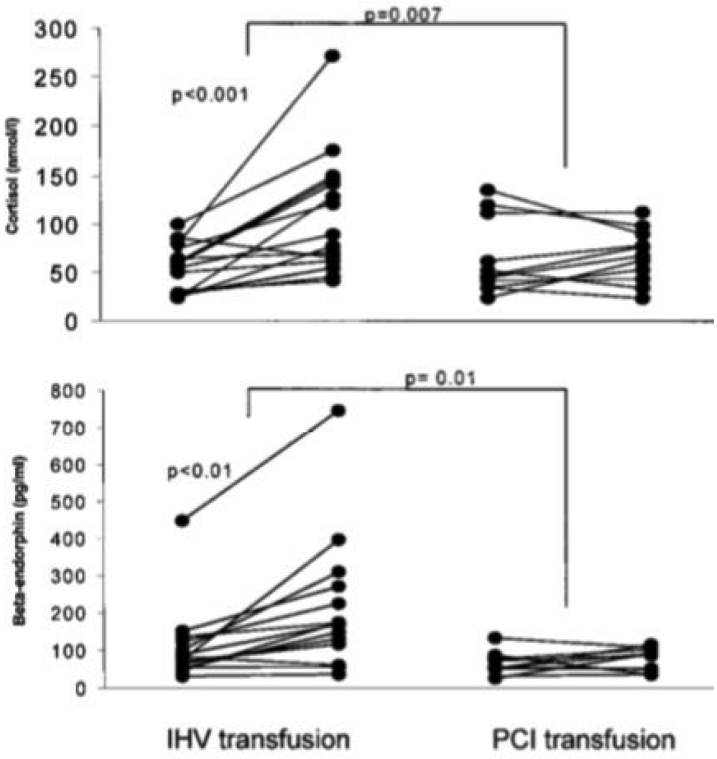

FIG. 3. Fetal plasma cortisol and β-endorphin concentrations befor and after transfusion at the IHV and the PCI.

Importantly, this study not only confirmed the findings of an earlier similar study, but by simultaneously measuring the maternal hormone levels (which stayed level between groups) they also showed that the fetal elevations were not due to increased maternal stress hormone levels.[19] Therefore, even while in the normal intrauterine chemical environment, noxious stimulation caused increases in stress hormones, echoing what has been documented in premature and term infants who have already been born. The consistent evidence of stress responses changed pediatricians', neonatologists', and anesthesiologists' medical practice; noxious stimulation is avoided or treated.

Despite the extensive evidence and resulting changes to medical practice, the updated 2020 International Association for the Study of Pain's (IASP) definition of pain continues to exclude immature human beings. The IASP restated that pain must have the 2 components of "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."[2] They also specifically clarify, "Pain and nociception are different phenomena. Pain cannot be inferred solely from activity in sensory neurons."[2] This separation of noxious stimuli induced physical responses from emotional, experiential awareness of pain originated with Merskey, the chair of the IASP Subcommittee on Taxonomy. He believes "pain [is] a psychological concept and not a physical measure and that the experience of pain [has] to be distinguished from noxious stimulation."[2] His previously published philosophy is that pain is a "psychic event and not a physical event" because "the

physical side is the physiologic mechanism of impulses and signaling—the sense data. The pain is not these sense data but the perceptual experience of discomfort."[20] According to Merskey and the IASP, how pain makes us consciously feel is indicative of whether or not pain exists, anatomical reception via neurologic messaging and resultant physiologic reaction to painful stimulation is irrelevant.

Dismissing neurologic impulses activated by noxious stimuli and their subsequent multi-organ stress responses as immaterial to the presence of pain is problematic for several reasons. For one, as already noted from Johnston & Steven's data, premature babies who were repeatedly poked for heel sticks at a time when they lacked a mature conscious awareness or ability to verbally recall and complain about previous pokes, had heightened responses to this painful procedure compared to unexposed premature babies.[7] Yet, "the earlier born infants had higher heart rates and lower oxygen saturations than the newly born infants, before as well as during, the procedure."[7] Taddio et al also found that newborns "exposed to repeated heel lances in the first 24 to 36 hours of life learned to anticipate pain and exhibited more intense pain responses during venipuncture than normal infants"[21] Both of these studies demonstrate what Van de Velde & De Buck called a "procedural memory".[22] From their review of the literature, they concluded that "although early painful memories are not accessible to conscious recall, they may be encoded in 'procedural memory' and lead to abnormal behavioral patterns or altered sensory processing in later life."[22]

Interestingly, the hypersensitization of the immature nervous system to noxious stimulation (especially when repetitive), that these authors document, makes physiologic sense given the nervous system's developmental stage. Fitzgerald, who has multiple published studies on this topic summarizes the developmental complexities stating, "a lack of balance between inhibitory and excitatory supraspinal controls may mean that infants are less able to mount effective endogenous control over noxious inputs than adults"[23]. Hatfield further explains that there is also a "receptor field" in the spinal cord of infants that is "larger than adult fields until 42 weeks gestation, [and] then declines to adult size by 43-44 weeks gestation… This accentuates the low pain threshold of preterm infants and is thought to be associated with the increased vulnerability of excitotoxic damage in the newborn brain."[24] Based on the evidence, the AAP's 2016 update, "*Prevention and Management of Procedural Pain in the Neonate*" also noted this "increased excitability of nociceptive neurons in the dorsal horn of the spinal cord accentuates the infant's sensitivity to subsequent noxious and non-noxious sensory stimuli."[6] Despite the philosophy of the IASP, immature human beings are not only pain capable, they have an increased sensitivity which makes them more vulnerable to its effects than adults.

In addition to premature infants' likely heightened pain sensitivity, the IASP's belief that pain exists only when there is an adult-level of conscious awareness is prima facie problematic. How can conscious awareness be adequately defined? Are we to perform abdominal surgery without anesthesia on patients with Alzheimer's Disease? When humans are immature and particularly when still in-utero, no one actually knows to what degree human beings are aware. However, as explained by Lowery et al in their neurodevelopmental review article, we do know that the developing neural elements may be immature, but they are not inactive.[25] In response to noxious stimulation, this immature but developmentally appropriate and scientifically documented activity is dismissed by IASP because the activity is not equivalent to an adult's neurologic response. Interestingly, Professors Peter Singer, Adam Shriver, and Nicholas Shea share this philosophy and were the IASP's ethical consultants. Professor Singer previously published, "the potential of a fetus to become a rational, self-conscious being, cannot count against killing it at a stage when it lacks these characteristics."[26] It is not surprising that "Singer and colleagues proposed" that the IASP definition state "to be in pain is to have a particular conscious experience…"[2]. The ability to describe an experience, whether it occurred as an adult or earlier in life when neurologically immature, does not determine whether or not something occurred.

Because no one can prove whether or not the subjective feeling of pain is an integral part of intrauterine life, the use of nociception (which refers to the anatomical and physiological responses to hurtful stimuli), is a better expression.[13] Nociceptive responses are consequential because they result in measurable, physiologic changes that affect the baby. Therefore, broadening this definition to acknowledge the ultimately damaging effects of noxious stimulation in the gestationally and developmentally immature infant, would provide greater accuracy.

Derbyshire and Bockmann agree, stating that the IASP's definition "restricts pain almost exclusively to fairly mature human beings" and the "evidence…points towards an immediate and unreflective pain experience mediated by the developing function of the nervous system from as early as 12 weeks."[3] This particular statement is remarkable for several reasons. For one, the authorsadmit that their views on abortion ethics are divergent and that "fetal pain has long been a contentious issue, in large part because fetal pain is often cited as a reason to restrict access to termination of pregnancy or abortion."[3] In fact Derbyshire, an abortion advocate, previously published that pain perception was dependent upon processing in the cortex cerebri[27] and others agreed.[28] However, informed by a more recent review of the data, Derbyshire came to a different conclusion. He and co-author Bockman could not support a categorical rejection of fetal pain. They noted that the IASP's definition was appropriate for adult patients presenting with pain, but it does not consider the kind of pain an in utero infant might plausibly experience.[3]

Previously, 24 weeks gestation was the earliest fetal pain was thought possible due to the timing of connections forming between the thalamus (which receives information from peripheral pain receptors via the spinal cord), and the cerebral cortex. However, there is now evidence that pain does not require the cortex, *sub*cortical structures are sufficient.[3,18,25,29] These subcortical structures include the brain stem, basal ganglia, amygdala, and the hypothalamic-pituitary axis, all of which may be capable of processing pain-instigated impulses from noxious stimuli several weeks prior to the development of thalamic-cortical connections.[25,29,30] Because subcortical processing of pain occurs without conscious intent, these impulses are, by definition, reflexes. However, not all reflexes are the same. Instigating the patellar reflex can amuse grammar school children, triggering subcortical pain processing by noxious stimulation can affect an immature human's development.[29]

Relying on connections to the cortex for the existence of pain is also refuted by clinical evidence in adults suggesting that neither ablation nor stimulation of the primary somatosensory cortex alters pain perception.[18] Reliance on the cortex for pain is also disproved by infants who are either missing or have minimal cortex (anencephalic and hydranencephalic babies) who have been exposed to painful and consoling stimuli and then respond appropriately.[18,30] Taken together, the findings of these studies suggest that definitions of pain which hinge on possessing a mature conscious capacity requiring cortical functioning and connectedness, are outdated.

CONCLUSION

It is unethical to intentionally harm an innocent human being irrespective of the individual's ability to perceive pain. However, a large body of scientific evidence demonstrates that painful or noxious stimulation adversely affects immature human beings, both before and after birth. This paper highlights both where the standard of care for pain management in this population once was, where it is now, and the evidence behind the changes. Natural law ethics are not addressed here, nor are the related political and legal rights of humans before and after birth. This paper specifically presents the scientific data that has resulted in dramatic medical practice improvements in neonatal and pediatric pain management. That medical practice significantly changed despite these ongoing political, legal, and ethical disputes

only illustrates the strength of this data is. Regarding specifically pain capability during intrauterine life, Derbyshire and Bockman note, "Whether there was ever consensus... it is now clear that the consensus is no longer tenable."[3] The IASP's definition of pain is too narrow specifically because even without conscious awareness, "especially in fetuses, noxious stimuli may have adverse effects on the developing individual regardless of the quality of the level of processing in the brain."[29] The likelihood of noxious stimulation-induced changes in developing human beings cannot be ethically ignored. In Anand's 1987 landmark publication, the authors acknowledged the difference between "nociceptive activity" and pain's "strong emotional associations" but also immediately noted that belaboring this point had already "obscured the mounting evidence that nociception is important in the biology of the neonate".[4] Informed by the evidence, ACPeds advocates the need for in-utero, neonatal, and pediatric pain prevention, mitigation, and treatment. Medicine's double standard of acknowledging pain capability in wanted premature babies while denying it in unwanted unborn babies of the same gestational age is unconscionable.

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The American College of Pediatricians is a national medical association of licensed physicians and healthcare professionals who specialize in the care of infants, children, and adolescents. The mission of ACPeds is to enable all children to reach their optimal, physical and emotional health and well-being.

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