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Preface

This edition features an article by Aaron Kheriaty, M.D., which reviews the relevant research literature on the relationship between abortion and various mental health outcomes. Despite multiple studies hypothesizing that abortion may be therapeutic for pregnant women with mental health conditions, there are no empirically established mental health benefits of abortion. There is, however, substantial empirical evidence that abortion worsens mental health outcomes for at least some women, particularly those with preexisting mental health conditions. While the nature and degree of mental health risks from abortion remains a disputed question, we offer some conclusions that find strong support in the existing research literature.

The second article, by Piotr Lisowski, L.D., contrasts perspectives on the legalization and decriminalization of soft drugs beyond their medical applications. Although there is ongoing public discussion over the benefits of legalizing soft drugs, Ukraine's current legal system does not represent a cohesive strategy. The study aims to conduct a substantiated review of the disadvantages and advantages of the legalization of soft drugs at the state level, with a forecast of risks associated with the introduction of permissive mechanisms for their use for recreational purposes, and to compare national peculiarities with the positions of legislators of other countries and existing experience in this area. To achieve this goal, the method of analyzing approaches and instruments for regulating drug trafficking at the supranational and local levels of different countries. The results of the research on this topic are as follows: content and peculiarities of the concepts of "legalization" and "decriminalization" for use in the context of the study of soft drugs were determined; generalized provisions on classification of soft drugs as a separate type of drugs were reflected; the positive and negative impact of legalization of these substances was assessed with due regard to the existing world experience; possible risks and recommendations for introducing soft drugs into free circulation through their legalization in Ukraine were formulated. The results obtained during the study constitute a substantial theoretical basis and can be used for further study of the problematic issues of soft drugs' authorization at the state level in Ukraine and abroad.

Alexander Gariti, MBE, HEC-C, in the third article, critically examines the ethical dimensions of utilizing Department of Motor Vehicles (DMV)-based First Person Authorization (FPA) for organ donation. While ostensibly designed to uphold patient autonomy, DMV-based FPA raises

significant ethical concerns due to its lack of informed consent and limited impact on organ donation rates. Drawing on principles of autonomy, informed consent, and medical ethics, this article argues for a reevaluation of current practices and proposes alternative approaches that prioritize genuine informed decision-making.

In the *Verbatim*, AAPLOG Committee Opinion 12 - Ethical Treatment of Human Embryos, the key scientific question addressed is whether the embryo is a human organism, i.e., a human being. The answer to this question has significant implications for the practice of Assisted Reproductive Technology (ART), especially In-Vitro Fertilization (IVF), and also for the creation and use of human embryos for research, as exemplified by the recent proposal introduced in the UK Parliament for the creation of human embryos in "industrial quantities" for experimentation. This Committee Opinion explores the scientific evidence surrounding the beginning of a human organism/human being and then the necessary implications of this information for the ethical treatment of embryos in both research and IVF.

This edition of *Issues in Law and Medicine* marks the 40th year of publication. The editorial committee thanks all our authors from the U.S. and around the world, our loyal and dedicated referees, domestic and foreign subscribers, the Library of Congress, the United States Supreme Court Library and law libraries across the county, the National Library of Medicine and many medical libraries, and a variety of on-line vendors, indices and abstracting services in the U.S. and abroad, for their cooperation and support providing an international platform for the scholarly discussion of contemporary issues in law and medicine these past 40 years. The success we have enjoyed is in no small measure attributable to each of you.

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

Articles

Abortion and Mental Health: What Can We Conclude?

Aaron Kheriaty, MD*

ABSTRACT: Recent legal challenges to state abortion laws argue that abortion is necessary to protect women's mental health. This paper reviews the relevant research literature on the relationship between abortion and various mental health outcomes. Despite multiple studies hypothesizing that abortion may be therapeutic for pregnant women with mental health conditions, there are no empirically established mental health benefits of abortion. There is, however, substantial empirical evidence that abortion worsens mental health outcomes for at least some women, particularly those with preexisting mental health conditions. While the nature and degree of mental health risks from abortion remains a disputed question, we offer some conclusions that find strong support in the existing research literature.

Legal Issues

In a recent lawsuit filed by abortion providers in Indiana state court, the plaintiffs challenged Indiana's law regulating abortion, SB-1, on the basis that it lacks an exception to permit abortion for women's mental health.[1] SB-1, which generally restricts abortion in Indiana, contains exceptions permitting abortion in cases of (1) rape and incest, (2) the diagnosis of a lethal fetal anomaly, and (3) when reasonable medical judgment dictates

* Aaron Kheriaty is a practicing psychiatrist and Director of the Bioethics and American Democracy Program at the Ethics and Public Policy Center.

[1] *Planned Parenthood et al. v. Members of the Medical Licensing Board of Indiana* (Monroe County Circuit Court, Cause No. 53C06-2208-PL-1756). Disclosure: I served as an expert witness for the defense (State of Indiana) in this case, submitting a declaration, undergoing a deposition, and testifying at trial on the themes and findings contained in this paper.

that performing the abortion is necessary to prevent death or a serious risk of substantial and irreversible physical impairment of a major bodily function (the "Health or Life Exception"). Plaintiffs in this lawsuit allege that this health or life exception is too narrowly tailored and thus violates the right to privacy in the Indiana Constitution. Their argument rests on the claim that abortion is often necessary to improve the mental health of pregnant women, particularly those with diagnosed mental health disorders. Here I examine whether this claim can be justified based on current empirical evidence on mental health and abortion.

Mental Health Effects of Abortion

To summarize the varied and disparate research literature on the relationship—if any—between abortion and mental health, I will focus on review articles, meta-analyses, medical record studies, and prospective longitudinal population-based studies. While the quality and results of some studies on these questions are mixed, I will argue that relevant conclusions can be drawn from the research as a whole.

As I will attempt to show, the current body of research suggests that a significant number of women suffer negative mental health consequences of abortion, with some identifiable risk factors. As the U.S. Supreme Court acknowledged in *Gonzales v. Carhart*, "It seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained. Severe depression and loss of esteem can follow" (IV.A).[2] Evidence from clinical, epidemiological, and social science research supports this conclusion. Some women who obtain abortions subsequently suffer psychologically complex and distressing consequences, and in many of these cases, psychological harms are pronounced and measurable. Identifiable medical, psychological, and social factors in the patient's history can also help predict which patients may be at elevated risk. By contrast, there are currently no available published studies suggesting that abortion improves mental health outcomes in some cases.

A. Reviews and Meta-Analyses

An early review article by Thorp and colleagues in 2003 found that abortion was associated with increased depression and could lead to self-harm behaviors. The authors concluded: "Induced abortion increased the risks for both a subsequent preterm delivery and mood disorders substantial enough to provoke attempts of self-harm. Preterm delivery and depression are important

[2] Citing brief for Sandra Cano et al. as Amici Curiae in No. 05–380, pp. 22–24.

conditions in women's health and avoidance of induced abortion has potential as a strategy to reduce their prevalence."[3]

A 2011 meta-analysis by Coleman[4] quantitatively synthesized research published between 1995 and 2009 on abortion and subsequent mental health outcomes. This analysis pooled 22 published studies, with over 800,000 participants and more than 161,000 women who had undergone abortions—the largest study to date of pooled data on the question of abortion and mental health. Coleman's meta-analysis examined whether abortion is associated with a higher subsequent risk for well-defined mental health problems: (1) anxiety disorders, (2) depression, (3) alcohol abuse, (4) marijuana abuse, and (5) suicide behaviors.

The results showed that women with an abortion history experienced an 81% increased risk for mental health problems of various kinds compared to women who had not had an abortion. The study found statistically significant effects for all five areas measured: anxiety disorders increased by 34%, depression increased by 37%, alcohol abuse increased by 110%, marijuana abuse increased by 220%, and suicidal behaviors increased by 155%.

In addition to comparing women who had an abortion with women who did not, it is also instructive to compare women who had an abortion to women who had an unintended pregnancy but chose to carry the pregnancy to term. In Coleman's meta-analysis, when compared to women with unintended pregnancy brought to term, women who had an abortion still had a 55% increased risk of mental health problems. Women in the unintended pregnancy carried to term group were closer to the results for the no abortion group than they were to the abortion group. So regardless of the type of comparison cohort used, abortion was associated with a significant increased risk of mental health problems in this analysis.

Following publication, some critics dismissed Coleman's study, citing eight letters to the editor published in the same journal along with Coleman's response.[5] In her response to these letters, Coleman explained her methodological

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[3] J. M. Thorp, Jr., K. E. Hartmann, and E. Shadigian, "Long-Term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence," *Obstet Gynecol Surv* 58, no. 1 (2003).no. 1 (2003

[4] Priscilla K. Coleman, "Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009," *British Journal of Psychiatry* 199, no. 3 (2011).

[5] Abel, K. M., Susser, E. S., Brocklehurst, P., & Webb, R. T. (2012). Abortion and mental health: Guidelines for proper scientific conduct ignored. *British Journal of Psychiatry*, 200(1), 74-75. doi:10.1192/bjp.200.1.74a; Goldacre, B., & Lee, W. (2012). Abortion and mental health: Guidelines for proper scientific conduct ignored. *British Journal of Psychiatry*, 200(1), 77-77. doi:10.1192/bjp.200.1.77; Howard, L. M., Rowe, M., Trevillion, K., Khalifeh, H., & Munk-Olsen, T. (2012). Abortion and mental health: Guidelines for proper scientific conduct ignored. *British Journal of Psychiatry*, 200(1), 74-74. doi:10.1192/bjp.200.1.74; Lagro-Janssen, T., Weel, C. V., & Wong,

choices and the reasons these were suitable for analyzing the available literature.[6] After considering the critiques, the journal editors maintained that Coleman's paper utilized sound research methods and passed a thorough peer review process, and they appropriately refused to retract her paper in response to these critics.[7] Again last year critics again pressured the journal for retraction and again the *British Journal of Psychiatry* declined to retract.[8] Instead of considering Coleman's findings in the context of other available research, and weighing the study's particular strengths and limitations, many critics dismissed it wholesale due to methodological critiques. A better response would have involved publishing another meta-analysis using inclusion criteria or statistical methodology the authors believed to be more suitable; but Coleman's critics have yet to publish their own meta-analysis.

In the same year (2011) that Coleman's meta-analysis was published, another systemic review was published by the Academy of Medical Royal Colleges (AMRC) in the U.K.[9] The results of this study were mixed: while this

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S. L. (2012). Abortion and mental health: Guidelines for proper scientific conduct ignored. *British Journal of Psychiatry*, 200(1), 78-78. doi:10.1192/bjp.200.1.78a; Polis, C. B., Charles, V. E., Blum, R. W., & Gates, W. H. (2012). Abortion and mental health: Guidelines for proper scientific conduct ignored. *British Journal of Psychiatry*, 200(1), 76-77. doi:10.1192/bjp.200.1.76; Puccetti, R., Poggetto, M. C., & Pietro, M. L. (2012). Abortion and mental health: Guidelines for proper scientific conduct ignored. *British Journal of Psychiatry*, 200(1), 78-78. doi:10.1192/bjp.200.1.78b; Robinson, Stotland, & Nadelson, supra note 148.

[6] P. Coleman, "Author's Reply," *British Journal of Psychiatry* 200, no. 1 (2012). Contrary to claims that her methods were inappropriate, Coleman's methods followed the standard methods described in the *Handbook of Research Synthesis and Meta-Analysis.* The statistical instruments she utilized took into account of the types of studies available for systematic analysis on this particular question. Since many of the available studies were heterogenous in terms of outcomes measured, she utilized a statistical approach known as a random effects model that is more appropriate for weighing heterogenous studies, as compared to a fixed-effects model that is more appropriate for synthesizing studies with one common measured effect. Also, in order to address the issue of heterogeneity in the available studies, Coleman's study ran separate meta-analyses based on distinct comparison groups and outcomes. Any choice in study methods or statistical instruments has certain trade-offs, and the chosen methods always influence the conclusions that can or cannot be drawn from the findings. To suggest, as Coleman's critics did, that her methods were wholly unsound or her conclusions entirely unworthy of consideration is to apply unreasonable methodological standards. There is no perfect method and no perfect study design for a project as complex as a meta-analysis. Careful attention to statistical methods employed can help us discern nuances of interpretation of the findings; but they are not a reason to dismiss the findings wholesale.

[7] Tyrer, P., & Waheed, W. (2012). Editors' response. *British Journal of Psychiatry*, 200(1), 78-79. doi:10.1192/bjp.200.1.78c

[8] Quinn, Ryan, "Weighing Retracting an Abortion Critic's Work, With Lawyers Involved," *Inside Higher Ed*, July 31, 2023. Available at https://www.insidehighered.com/news/faculty-issues/research/2023/07/31/mulling-retracting-abortion-critics-work-under-legal-eyes

[9] "Induced abortion and mental health: a systemic review of the mental health outcomes of induced abortion, including their prevalence and associated factors," developed for the

review did not find an overall increase in mental health problems following abortion as compared to live birth (when previous mental health problems were controlled for), it did identify a subset of women with particular risk factors who are likely at increased risk of mental health problems following abortion as compared to live birth. For example, women who show a negative emotional reaction immediately following an abortion are at elevated risk for worse mental health outcomes, as are women with previous mental health problems.[10] The authors note, "Identifying these factors would enable health-care professionals to monitor and provide greater support for women identified as potentially 'at risk'."[11] The AMRC concluded that there was no association with pregnancy outcome and mental health problems, thereby conceding that abortion did not improve mental health: "When a woman has an unwanted pregnancy, rates of mental health problems will be largely unaffected whether she has an abortion or goes on to give birth."[12]

Fergusson and colleagues published in 2013[13] a reappraisal of the studies used in the Coleman and ARMC meta-analyses. The authors hypothesized that abortion may *reduce* adverse mental health consequences as compared to live birth. Instead, this study found that abortion was associated with statistically significant increases in the risks of alcohol misuse (2.3 times higher), illicit drug use/misuse (3.91 times higher), and suicidal behavior (1.69 times higher), as well as elevated risks of anxiety (though this was not statistically significant)—findings which supported a link between abortion and poor mental health outcomes.[14] In disconfirming the authors' hypothesis that women might benefit psychologically from abortion, this study also confirmed the finding of every other review or meta-analysis of the issue of abortion and mental health:

Academy of Medical Royal Colleges by National Collaborating Centre for Mental Health, London, 2011. https://www.aomrc.org.uk/wp-content/uploads/2016/05/Induced_Abortion_Mental_Health_1211.pdf

[10] The authors also mention in this context also "life events, pressure from a partner to have an abortion, and negative attitudes towards abortions in general and towards a woman's personal experience of the abortion (121)" as risk factors for which there is some evidence.

[11] Ibid., p. 121.

[12] Ibid., p. 125.

[13] D. M. Fergusson, L. J. Horwood, and J. M. Boden, "Does Abortion Reduce the Mental Health Risks of Unwanted or Unintended Pregnancy? A Re-Appraisal of the Evidence," *Aust N Z J Psychiatry* 47, no. 9 (2013).

[14] The authors note that these findings may have legal implications for abortion in those jurisdictions where abortion is justified on mental health grounds: "These conclusions have important, if uncomfortable, implications for clinical practice and the interpretation of the law in those jurisdictions (England, Wales, Scotland, Australia, New Zealand) which require abortion to be authorized on medical grounds. In these jurisdictions, the great majority of abortions are authorized on mental health grounds (Statistics New Zealand, 2003; South Australian Abortion Reporting Committee, 2008; Department of Health, 2011). The present re-analysis suggests that, currently, there is no evidence that would support this practice" (825).

abortion is not therapeutic from a mental health perspective. Research on this issue has never found abortion to confer mental health benefits and has often found it to confer mental health risks.

B. Medical Records Studies

One of the major challenges in doing research on abortion, including mental health outcomes research, is that abortion tends to be under-reported. Typically, respondents will report under half, and as few as 30%, of the number of abortions expected based on age-adjusted national data on abortion rates.[15] Several studies have found that the cohort of women refusing to participate in follow-up studies are more likely to have experienced negative psychological reactions to their abortions.[16] It's not surprising that women who have had more negative reactions tend not to want to participate in abortion studies, since study questionnaires can trigger their negative thoughts and feelings.[17] This results in a sampling selection bias for most research on abortion and mental health, skewing results toward finding lower rates of mental health problems associated with abortion than is actually the case.

One way for researchers to bypass this problem of selection and reporting bias is to examine medical records directly. Three well-designed studies using medical records have examined the connection between abortion and the risk for subsequent suicide. A Finnish record study showed that women who had an abortion were three times more likely to commit suicide within one year of the abortion than women in the general population, and more than six times more likely to commit suicide than women who carried their pregnancies

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[15] J. R. Steinberg and J. M. Tschann, "Childhood Adversities and Subsequent Risk of One or Multiple Abortions," *Soc Sci Med* 81 (2013).

E. F. Jones and J. D. Forrest, "Underreporting of Abortion in Surveys of U.S. Women: 1976 to 1988," *Demography* 29, no. 1 (1992).

R. K. Jones and K. Kost, "Underreporting of Induced and Spontaneous Abortion in the United States: An Analysis of the 2002 National Survey of Family Growth," *Stud Fam Plann* 38, no. 3 (2007).

[16] Söderberg H, Andersson C, Janzon L, et al. Selection bias in a study on how women experienced induced abortion. *Eur J Obstet Gynecol Reprod Biol* 1998; 77(1): 67–70. Adler NE. Sample attrition in studies of psychosocial sequelae of abortion: how great a problem? *J Appl Soc Psychol* 1976; 6(3): 240–259.

[17] One reproductive history survey that included the question, "Answering this survey has been emotionally difficult or disturbing," found that women admitting a history of abortion were significantly more likely to feel distraught or disturbed by participating in the survey. Cf. Reardon DC and Ney PG. Abortion and subsequent substance abuse. *Am J Drug Alcohol Abuse* 2000; 26(1): 61–75. Cf. also Broen, A.N., Moum, T., Bødtker, A.S., & Ekeberg, Ø. "The course of mental health after miscarriage and induced abortion: a longitudinal, five-year follow-up study." *BMC Medicine*, 3,18 (2005). doi: 10.1186/1741-7015-3-18. Retrieved from http://www.biomedcentral.com/1741-7015/3/18

to term.[18] Another Dutch record study found increased risk of recurrence of mental health disorders following abortion in women with a history of mental illness, consistent with other studies that suggest this as a risk factor.[19]

A medical records study done in Denmark showed that women who had abortions were at higher risk for admission to psychiatric hospitals within three months than women who carried their pregnancies to term.[20] (This finding is especially significant since the postpartum group is already at elevated risk for psychiatric hospitalization due to postpartum depression.) Finally, another study of abortion and suicide that utilized Medicaid claims for 173,000 women in California found that women who had abortion were 154% more likely to commit suicide compared to women who delivered.[21]

Findings from these studies are consistent with robust and consistent findings from other suicide research which shows that motherhood lowers the risk for suicide. One review of suicide risk factors noted: "Being pregnant and having young children in the home also are protective against suicide."[22] Another study on the impact of parental status on suicide risk found: "The presence of children is protective against suicide in parents in terms of having children and, to a higher degree, having a young child; these effects exist even when adjusted for marital, socioeconomic, and psychiatric status; and their influences are much stronger in women than in men."[23]

C. Longitudinal Population-Based Studies

While there is evidence for an association between abortion and negative mental health outcomes, it is considerably more difficult to obtain definitive conclusions on whether abortion directly *causes* worse mental health outcomes. It is worth noting that Coleman, among others cited above, recognizes this limitation and discusses it when presenting the findings in her paper.[24] The correlation/causation problem is a well-known challenge in social science and

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[18] M. Gissler, E. Hemminki, and J. Lonnqvist, "Suicides after Pregnancy in Finland, 1987-94: Register Linkage Study," *BMJ* 313, no. 7070 (1996).

[19] J. van Ditzhuijzen et al., "Incidence and Recurrence of Common Mental Disorders after Abortion: Results from a Prospective Cohort Study," *J Psychiatr Res* 84 (2017).

[20] H. P. David, N. K. Rasmussen, and E. Holst, "Postpartum and Postabortion Psychotic Reactions," *Fam Plann Perspect* 13, no. 2 (1981).

[21] D. C. Reardon et al., "Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women," *South Med J* 95, no. 8 (2002).

[22] M. K. Nock et al., "Suicide and Suicidal Behavior," *Epidemiol Rev* 30 (2008).

[23] P. Qin and P. B. Mortensen, "The Impact of Parental Status on the Risk of Completed Suicide," *Arch Gen Psychiatry* 60, no. 8 (2003).

[24] Coleman, "Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009." She writes: "when the independent variable cannot be ethically manipulated, as is the case with abortion history, definitive causal conclusions are precluded from both individual studies and from a quantitative synthesis such as this one" (pp. 185-6).

epidemiology. The easiest method to prove causation utilizes *prospective* studies where the independent variable—in this case, abortion—is manipulated. For this to happen, women would have to be *randomly* assigned to an abortion vs. no-abortion group and subsequently followed to see what happens (known as a randomized controlled trial or RCT). It would obviously be unethical and unacceptable ever to conduct such research. In the absence of such research, however, it is still possible to establish causation. Much valuable epidemiological research works without recourse to RCTs.

The next best kind of study for establishing causation is a population based, nationally representative longitudinal study with multiple temporal study points, while controlling for potential confounding factors. Longitudinal design also bypasses the difficulty of assessing and controlling for pre-abortion mental health status, since it includes multiple data points across time.

In 2016, Sullins published this kind of longitudinal study[25] using data collected from a highly representative random sample of 8,005 American women (using The National Longitudinal Study of Adolescent to Adult Health) who were followed from ages 15 to 28 years. Results of this study showed that abortion is consistently associated with a moderate increase in risk of mental health disorders during late adolescence and early adulthood. After controlling for possible confounding variables (age, race, region of origin, parent education, and childhood poverty status) this study found increased rate of mental disorders associated with abortion (54%) and pregnancy loss (16%), but a decreased risk for live birth (19% less). The effect of repeated abortions was substantially additive, supporting the theory that emotional distress is associated with the abortions themselves, and not merely with accompanying conditions that may also be associated with the propensity to have an abortion.

A similar randomly sampled population-based study was conducted by Canadian researchers in 2010 based on National Comorbidity Survey Replication data. Statistically significant associations were again found between abortion history and a wide range of mental health problems after controlling for the experience of interpersonal violence and demographic variables. When compared with women without an abortion history, women with a prior abortion experienced several statistically significant elevated risks, including a 61% increased risk of mood disorders, a 61% increased risk of social phobia, and 59% increased risk of suicidal ideation. Abortion was also linked to significant in-

[25] D. P. Sullins, "Abortion, Substance Abuse and Mental Health in Early Adulthood: Thirteen-Year Longitudinal Evidence from the United States," *SAGE Open Med* 4 (2016). Sullins describes his study sample: "The National Longitudinal Study of Adolescent to Adult Health (Add Health), initiated in 1994 with funding from 18 federal agencies, was designed to be the largest and most extensive study of the health-related behaviors of US adolescents during the transition to adulthood."

creased risks for alcohol misuse (261%), alcohol dependence (142%), drug misuse (313%), drug dependence (287%) and any substance use disorder (280%).[26]

D. Narrative Reviews and Negative Studies

Those who are skeptical of a link between abortion and poor mental health outcomes often cite a 2008 report from the American Psychological Association on abortion and mental health. However, to cite the APA report directly: "It is clear that some women do experience sadness, grief, and feelings of loss following termination of a pregnancy, and some experience clinically significant disorders, including depression and anxiety."[27] The somewhat misleading claim regarding this study is typically based upon a single widely reported finding highlighted in the report's press release: "The relative risk of mental health problems among *adult* women who have a *single*, legal, *first-trimester* abortion of an *unwanted* pregnancy for *nontherapeutic* reasons is no greater than the risk among women who deliver an unwanted pregnancy" [italics added]. To draw from this the conclusion that abortion in general does not have a negative impact on women's mental health is mistaken, because the many qualifiers included in this statement actually end up *excluding the majority of women seeking abortion on any given day*. As Reardon has cogently argued:

> This reassuring conclusion was actually couched in nuances which make it applicable to only a minority of women undergoing abortions on any given day. It excludes the 48%–52% of women who already have a history of one or more abortions, the 18% of abortion patients who are minors, the 11% of patients beyond the first trimester, the 7% aborting for therapeutic reasons regarding their own health or concerns about the health of the fetus, and the 11%–64% whose pregnancies are wanted, were planned, or for which women developed an attachment despite their problematic circumstances.[28]

If we remove any one or any combination of these qualifiers, the risk of mental health problems following abortion significantly increases.

In addition to the aforementioned qualifiers, the APA report identified several other risk factors for mental health problems after abortion, including, among others: perceived pressure from others to terminate a pregnancy; lack of perceived social support from others; low perceived or anticipated social

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[26] N. P. Mota, M. Burnett, and J. Sareen, "Associations between Abortion, Mental Disorders, and Suicidal Behaviour in a Nationally Representative Sample," *Can J Psychiatry* 55, no. 4 (2010).

[27] Major B, Appelbaum M, Beckman L, et al. Report of the APA Task Force on mental health and abortion. Washington, DC: American Psychological Association, 2008, 105 pp, http://www.apa.org/pi/women/programs/abortion/mental-health.pdf

[28] D. C. Reardon, "The Abortion and Mental Health Controversy: A Comprehensive Literature Review of Common Ground Agreements, Disagreements, Actionable Recommendations, and Research Opportunities," *SAGE Open Med* 6 (2018).

support for the abortion decision; a prior history of mental health problems, personality factors such as low self-esteem and low perceived control over her life; use of avoidance and denial coping strategies; ambivalence about the abortion decision; low perceived ability to cope with the abortion prior to its occurrence; a history of prior abortion; abortion after the first trimester; terminating a pregnancy that is wanted or meaningful; and feelings of commitment to the pregnancy.

There are several narrative review articles that do not find a significant association between abortion and negative mental health outcomes—though as stated before, none of them found that abortion *improved* mental health outcomes. In examining the contribution of these studies it is important to understand the limitations of narrative reviews, in contrast to a meta-analysis like Coleman's cited above. In a review article, studies with positive conclusions are individually summarized as well as studies with negative conclusions. But how these studies are weighted in a narrative review, and how overall conclusions are drawn, is largely left up to the discretion of the author.

A meta-analysis is a quantitative or numerical synthesis of data from many previously published studies. All studies are not treated equally; they are weighted statistically based upon their sample size and rigor. Data from several studies can be aggregated and analyzed together using statistical methods. The author of a meta-analysis must disclose clearly what the inclusion and exclusion criteria are, and how the data are being statistically analyzed, so that other researchers can replicate the study if they desire. Conclusions are presented according to aggregated quantitative findings, so as not to be unduly influenced by subtle biases of the authors. These methods make a meta-analysis like Coleman's less subject to authorial bias than the narrative review studies we examine here.

For example, a review article by Charles and colleagues often cited by abortion advocates (and published in a journal funded by abortion advocates) shows some of these methodological limitations.[29] The ranking system employed in this study ignored two central methodological considerations in prospective research designs: percentage of subjects consenting to participate, and retention of study participants over time.

Abortion advocates also frequently cite the "Turnaway" study—a study of 956 total women, funded by private foundations with a long history of abortion advocacy[30]—to argue that abortion is not associated with poor mental health

[29] V. E. Charles et al., "Abortion and Long-Term Mental Health Outcomes: A Systematic Review of the Evidence," *Contraception* 78, no. 6 (2008).

[30] Research and institutional funding was provided by the David and Lucille Packard Foundation, the William and Flora Hewlett Foundation, the Wallace Alexander Gerbode Foundation, and other private donors. https://www.ansirh.org/research/turnaway-study accessed 13 July 2019. The abortion advocacy group Advancing New Standards in Reproductive Health

outcomes. However, the Turnaway study has serious methodological weaknesses which should be considered when interpreting its findings. We should note especially the low rates of initial enrollment and high rates of dropout in this study: despite a financial inducement (study participants were offered $50), over two-thirds (69%) of the women approached at the abortion clinics refused to participate in at least one interview, and half of those who agreed to enroll in the study later dropped out.[31] This introduces a significant selection bias into the study sample, since we know that women who are ambivalent or struggling with the abortion decision are less likely to enroll in research studies on abortion.[32]

The selection bias may have been further amplified by the recruitment methods. According to the portion of study protocol that the researchers published: "It is up to the clinic staff at each recruitment site to keep track of when to recruit abortion clients to match to the turnaways [women who sought an abortion but were over the state's gestational age limit] recruited."[33] This enrollment method allowed clinic staff to exercise considerable leeway in deciding which women to invite to participate in the study. The lack of random sam-

(ANSIRH) has published over twenty papers based on a case series of women taking part in their Turnaway Study.

Cf. also, "Behind the Supreme Court's Abortion Decision, More Than a Decade of Privately Funded Research," Nina Martin, July 14, 2016, *ProPublica*. https://www.propublica.org/article/supreme-court-abortion-decision-more-than-decade-privately-funded-research, accessed 13 July 2019. The sympathetic profiled details "private donors who've spent more than a decade quietly pouring at least $200 million into the scientists' work, creating an influential abortion-research complex that has left abortion opponents in the dust," and mentions, among others, both the Packard Foundation and the Hewlett Foundation.

[31] Cf. Reardon DC, The Embrace of the Proabortion Turnaway Study: Wishful Thinking? or Willful Deceptions? *Linacre Q.* 2018 Aug;85(3):204-212. doi: 10.1177/0024363918782156. Epub 2018 Jun 20: "Only 31 percent of the invited pool actually participated in at least one interview. Thereafter, another 21 percent, 31 percent, 37 percent, 40 percent, and 46 percent of participants dropped out by the first-, second-, third-, fourth-, and fifth-year interviews, respectively. To summarize, only 27 percent of the invited women participated at the first six-month interview and only 17 percent participated through to the end of the five-year period. By any measure, this is an abysmal participation rate. … ANSIRH researchers simply have no reliable information about what 'most women' believe regarding their abortion decisions." These are extremely low participation and retention rates by any standard, and they seriously call into question the generalizability of the findings.

[32] Cf. Reardon DC and Ney PG. Abortion and subsequent substance abuse. *Am J Drug Alcohol Abuse* 2000; 26(1): 61–75. Cf. also Broen, A.N., Moum, T., Bødtker, A.S., & Ekeberg, Ø. "The course of mental health after miscarriage and induced abortion: a longitudinal, five-year follow-up study." *BMC Medicine*, 3,18 (2005). doi: 10.1186/1741-7015-3-18. Retrieved from http://www.biomedcentral.com/1741-7015/3/18

[33] Cited in Reardon DC, The Embrace of the Proabortion Turnaway Study: Wishful Thinking? or Willful Deceptions? *Linacre Q.* 2018 Aug;85(3):204-212. doi: 10.1177/0024363918782156. Epub 2018 Jun 20.

pling could easily exclude women whom staff anticipated would have difficulties during or following their abortion.

There are additional methodological problems with this study that seriously undermine its purported findings. In many cases, women turned away at the original clinic later obtained an abortion elsewhere; however, in the study these women were classified as "non-abortive". Furthermore, the study did not control for a history of previous abortions and did not control for repeat abortions obtained during the five-year follow up period. One study suggested that 40% of the turnaway group had a history of at least one previous abortion.[34] Likewise, a large percentage of women in the no abortion group would have had a previous abortion (48 to 52% of women according to findings from other studies[35]), making it impossible to distinguish effect of a past abortion from the effect of being denied an abortion. Thus, there were postabortion women in both the "abortion" group and in the "turnaway" group—who obtained an abortion either later in the pregnancy or during a prior pregnancy. The study should have controlled for previous abortions and followed up to see which women in the turnaway group later obtained an abortion elsewhere. Absent this information, a significant number of women were simply misclassified, and the study's conclusions were consequently badly compromised.

Given the nonrandom sampling, low rates of enrollment, high dropout rates, and misclassification of many participants, the Turnaway study suffers from serious methodological limitations that make it impossible to generalize to most women seeking abortion. Furthermore, for all its limitations, the Turnaway study did not find that access to abortion improved mental health outcomes for pregnant women.

E. Diagnosis of Fetal Anomalies

The research literature on mental health outcomes and abortion in the situations when a fetal anomaly/disability is detected show similar results. This research provides evidence that patients who opt for neonatal hospice fare better than those who choose abortion. While those who care for children with disabilities often deal with associated stress, they also frequently report that caring for such a child is immensely rewarding.

One study of 405 parents facing a life-limiting fetal condition who chose to carry the child to term found absence of regret in 97.5 percent of participants. The study authors noted: "Parents valued the baby as a part of their family and had opportunities to love, hold, meet, and cherish their child. Participants

[34] Rocca, Corinne H., Katrina Kimport, Heather Gould, and Diana G. Foster. "Women's Emotions One Week After Receiving or Being Denied an Abortion in the United States." *Perspectives on Sexual and Reproductive Health* 45 (3): 122–31 (2013). https://doi.org/10.1363/4512213.

[35] Jones R, Singh S, Finer L, et al. Repeat abortion in the United States. Occasional report no. 29. New York, 2006, http://www.popline.org/node/563305

treasured the time together before and after the birth. Although emotionally difficult, parents articulated an empowering, transformative experience that lingers over time."[36] Another study found similar results for parents who chose to continue a pregnancy after a lethal fetal diagnosis. The authors noted that, "After the birth, and at the time of the baby's death, parents expressed thankfulness that they were able to spend as much time with their baby as possible."[37] Researchers in another study were "surprised to find that the majority of parents were so happy to meet their baby, even joyful and at peace, even if he/she was stillborn or died within a few hours. No obvious pattern of parent characteristics, such as their religiosity, were associated with this response."[38]

We can contrast these findings with studies of women who choose abortion after a prenatal diagnosis of a fatal anomaly. One meta-analysis examined seventeen studies on the effects of abortion following prenatal diagnosis of fatal as well as non-fatal impairments. This study found that, "couples experienced selective termination as traumatic, regardless of the prenatal test revealing the fetal impairment or stage in pregnancy in which the termination occurred."[39] Moreover, the authors also noted that, "Women who terminated pregnancies following positive prenatal diagnosis... wanted to mourn but felt they did not deserve to mourn." The study also found that "couples, health care providers, family, and friends underestimated the intensity and duration of feelings of loss following selective termination."[40] In contrast to the generally positive experiences of women who carried such pregnancies to term described in the above studies, women in this study who elected abortion often suffered adverse psychological reactions, including inner conflict, remorse, and complicated grief, as the authors explain:

> The strategies women used to reconcile conflicts engendered by selective termination—denying the personhood of the baby, limiting the information they sought about the baby, transferring agency for choice to others, adopting a stance of moral relativity, avoiding disclosing or selectively disclosing the event to others—worked briefly but the women ultimately felt as if they were betraying themselves and their babies.[41]

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[36] C. Wool, R. Limbo, and E. M. Denny-Koelsch, ""I Would Do It All over Again": Cherishing Time and the Absence of Regret in Continuing a Pregnancy after a Life-Limiting Diagnosis," *J Clin Ethics* 29, no. 3 (2018).

[37] D. Cote-Arsenault et al., "We Want What's Best for Our Baby: Prenatal Parenting of Babies with Lethal Conditions," *J Prenat Perinat Psychol Health* 29, no. 3 (2015).

[38] D. Cote-Arsenault and E. Denney-Koelsch, ""My Baby Is a Person": Parents' Experiences with Life-Threatening Fetal Diagnosis," *J Palliat Med* 14, no. 12 (2011).

[39] M. Sandelowski and J. Barroso, "The Travesty of Choosing after Positive Prenatal Diagnosis," *J Obstet Gynecol Neonatal Nurs* 34, no. 3 (2005).

[40] Ibid.

[41] Ibid.

Another study examining outcomes of prenatal anomaly situations, which directly compared both groups, found: "Women who terminated reported significantly more despair, avoidance and depression than women who continued the pregnancy." The authors concluded, "There appears to be a psychological benefit to women to continue the pregnancy following a lethal fetal diagnosis. Following a lethal fetal diagnosis, the risks and benefits, including psychological effects, of termination and continuation of pregnancy should be discussed in detail with an effort to be as nondirective as possible."[42]

Conclusion

In summary, while there remains disagreement among researchers regarding abortion and mental health, there are substantial areas of concurrence among the major studies: (1) abortion is consistently associated with elevated rates of mental health problems compared to women without a history of abortion; (2) the abortion experience contributes to mental health problems for at least some women; (3) there are risk factors, such as pre-existing mental illness, that identify women at elevated risk of mental health problems after an abortion; (4) it is challenging to conduct research in this field in a manner that can definitively identify the extent to which any mental illnesses following abortion can be causally attributed to abortion itself, however, available research is strongly suggestive of a causal link between abortion and poor mental health outcomes for some women; and (5) most importantly, no available research demonstrates that abortion *improves* mental health outcomes for pregnant women.[43]

In short, the research strongly suggests that abortion will worsen, not improve, women's mental health overall—at least for a subset of women. On the other hand, research has not shown abortion to have any therapeutic benefit for women's mental health. This undermines legal arguments that abortion is therapeutically necessary for addressing or treating women with mental health conditions, as in the recent case against Indiana's abortion law cited at the beginning of this paper.

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[42] H. Cope et al., "Pregnancy Continuation and Organizational Religious Activity Following Prenatal Diagnosis of a Lethal Fetal Defect Are Associated with Improved Psychological Outcome," *Prenat Diagn* 35, no. 8 (2015).

[43] Cf. Reardon, "The Abortion and Mental Health Controversy: A Comprehensive Literature Review of Common Ground Agreements, Disagreements, Actionable Recommendations, and Research Opportunities."

Advantages and Disadvantages of Soft Drugs Legalisation at State Level

Piotr Lisowski, L.D.*

ABSTRACT: The relevance of the study lies in the contrasting perspectives on the legalisation and decriminalisation of soft drugs beyond their medical applications. Although there is ongoing public discussion over the benefits of legalizing soft drugs, Ukraine's current legal system does not represent a cohesive strategy. The study aims to conduct a substantiated study of the disadvantages and advantages of the legalisation of soft drugs at the state level, with a forecast of risks associated with the introduction of permissive mechanisms for their use for recreational purposes, and to compare national peculiarities with the positions of legislators of other countries and existing experience in this area. To achieve this goal, the method of analysing approaches and instruments for regulating drug trafficking at the supranational and local levels of different countries. The results of the research on this topic are as follows: content and peculiarities of the concepts of "legalisation" and "decriminalisation" for use in the context of the study of soft drugs were determined; generalised provisions on classification of soft drugs as a separate type of drugs were reflected; the positive and negative impact of legalisation of these substances was assessed with due regard to the existing world experience; possible risks and recommendations for introducing soft drugs into free circulation

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through their legalisation in Ukraine were formulated. The results obtained during the study constitute a substantial theoretical basis and can be used for further study of the problematic issues of soft drugs' authorisation at the state level in Ukraine or abroad.

Keywords: **narcotic substances, decriminalisation, drug legislation, cannabis, opiates**

Introduction

The issue of the free circulation of drugs has always caused a lot of debate in society due to the ambiguity of their impact on society and individuals. When considering the conflicting arguments in support or opposition to drug legalisation, the problem always arises of determining not only the legal or economic feasibility but also the social moral and ethical aspects of the relevant legalisation, since the use of drugs is perceived differently existing cultures and societies of individual states, as well as by modern medical doctrine.

Buchwald addressed the issue of distinguishing between drugs based on their chemical properties and therapeutic effects, highlighting some aspects of the division of drugs into "soft" and "hard" drugs.[1] The historical background and legal basis for the classification of narcotic drugs by their severity are highlighted by de Quadros Rigoni in a study on the peculiarities of the Dutch policy on these issues.[2] His work draws attention to one of legalization's main benefits—establishing regulated settings to lessen harm—while simultaneously highlighting a drawback: possible stigmatization or outside pressure from other jurisdictions with more stringent laws. Sheikhan et al.[3] discussed the problem of widespread cannabis advertising among young people, given the lack of age restrictions for viewing it and the problem of popularising this soft drug in open sources. Jorgensen and Wells[4] advocate for the legalisation of soft drugs, emphasizing their belief that marijuana use does not inherently lead to the consumption of harder substances. They contend that there is no solid link between cannabis usage and more potent narcotics, but they also point out the drawbacks of making cannabis use illegal. Their data indicates that the move to stronger drugs is more significantly influenced by environmental factors, genetic susceptibility, and the age at which drug use began. The same opinion regarding the lack of a proven relationship between soft and hard drug use is shared by Nöel and Wang,[5] and Williams.[6]

The international drug control conventions provide states with some flexibility in determining actions to deal with drugs, depending on the extent of the consequences of such actions and individual circumstances concerning

possible alternatives to conviction and punishment of violators of the established rules of circulation.[7] Ukraine is a party to the Single Convention on Narcotic Drugs,[8] according to which the parties shall take the legislative and administrative measures necessary to comply with the provisions of the said Convention to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution and trade in narcotic drugs. The United Nations Convention on Psychotropic Substances[9] was adopted to implement the prohibition and control of the circulation of narcotic substances, against the abuse of which the international efforts of most UN member states are directed. In addition to these fundamental documents in the field of combating drug trafficking, the United Nations adopted the Convention against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances,[10] which establishes the criminal nature of their manufacture, storage and sale. Currently, the growing role of international drug conventions is becoming increasingly important given the development of the illegal sector of the economy producing new types of drugs and the variety of ways they are sold. These legal acts contain conditions and mechanisms for restricting the illegal use of narcotic substances, as well as provide for the activities of international monitoring bodies and the international control system. Reducing the use of drugs exclusively for medical and scientific purposes is the main goal of the regulation enshrined in international conventions.[11] Given the existing developments in the field of state regulation of drug trafficking and the absence of prior legalisation of drugs in Ukraine, the research novelty lies in the analysis of the current international experience with a view to its further use in the development of new national legislation on drug trafficking to predict and avoid possible negative consequences of allowing the use of soft drugs for recreational purposes.

To assess the possible consequences of legalising drug usage, it is necessary to address their nature and legal distinction in the current norms, based on which they are classified as soft drugs. Identifying the criteria for distinguishing drugs that are safe or safe for human health from other drugs is a prerequisite for understanding the possible risks of their use within a country. At the same time, an important prerequisite for an objective understanding of the shortcomings of the introduction of legal drug trafficking among the civilian population is to understand the essence of the concept of "legalisation" in the context of the given research topic and to outline its features in comparison with decriminalisation, which characterises the form of abolition of punishment for the production, distribution and possession of drugs. The nature of liability for certain offences in a certain way indicates the Ukrainian legislator's attitude to certain types of unlawful acts, which reflects the State policy in the field of preventing the spread of the negative effect of illegal drug-related activities on public relations in the field of protection of public health as an object of encroachment.

The national legislation of Ukraine does not provide for provisions that would allow the use of narcotic substances for purposes other than medical, scientific or industrial. Ukrainian administrative and criminal regulations contain an express prohibition on the manufacture, storage and distribution of drugs of any kind.[12] Economic activity within the permitted purposes of using narcotic substances is regulated.[13] Given the peculiarities of Ukrainian regulations on drug trafficking, Ukraine has stricter legal sanctions than those in the European Union, Canada and certain administrative-territorial units of the United States. In this regard, the issue of drug legalisation should be preceded by substantive legal research and the development of sound recommendations on mitigating or abolishing penalties for violations of the current conditions of drug trafficking.

The purpose of this study was to perform a comprehensive analysis of the advantages and disadvantages of legalising soft drugs at the state level, with an assessment of the possible risks associated with the introduction of permits for their recreational use.

Materials and Methods

The methodological tools for the study of this article are represented by a substantive analysis of the existing provisions that directly or indirectly indicate the advantages or disadvantages of legalising soft drugs at the state level. To obtain reliable results, the primary issue of consideration during the study was the search for relevant theoretical and practical information on drugs that can be distinguished from others and classified as "soft drugs." The comparison method was used to identify several features inherent in this type of illicit substance, to identify the specifics of legal control over drug trafficking in different states and within the framework of supranational regulation, and to highlight statistics on the nature of the limits of permitted trafficking in other countries. Employing deduction, based on the foreign experience of legislative and law enforcement bodies, the main recommendations regarding the conditions for the possible legalisation of soft drugs in Ukraine were outlined. In determining the sources of the distinction between the main types of drugs, the historical method of scientific research was used to substantiate the legal basis for the commonly used division into "soft" and "hard" drugs, which was first reflected in Dutch legislation. This makes it particularly important to study the regulation of drug trafficking in the Netherlands, given the flexible current policy of this state towards recreational cannabis use. By specifying the main problems associated with drug trafficking in other countries (USA, Canada, the Netherlands), it was possible to model the best options for legalising soft drugs, considering the current situation in Ukraine.

The main material was based on the publications of several researchers who paid special attention to the issue of the legalisation of drugs or compre-

hensively covered the key features of the impact of drugs on society in terms of possible legal, medical or social consequences. The study was carried out in two stages, during which theoretical and practical data were reviewed and analysed in a sequential manner, which made it possible to substantiate the connection between the arguments about the expediency or inappropriateness of allowing the free use of soft drugs for recreational purposes and the state of such phenomena as the crime situation (crime rate), drug addiction and other relevant consequences.

The first stage is characterised by a comprehensive analysis of previously collected sources and includes a systematisation of theses on the peculiarities of the classification of drugs, control over their storage and use, and the impact of these processes on the development of crime. The study, based on the available information, employed generalisation in the form of graphic diagrams demonstrating the change in the limits of drug authorisation depending on the country, as well as fluctuations in the local crime rate in the context of free drug possession (on the example of the Netherlands). The study carried out at this stage identified current problems that make it impossible to fully foresee all the possible consequences of the state's legalisation of soft drugs. At the same time, the main recommendations for possible legalisation are given in the following discussion and reflected in the conclusions.

In the second stage, all aspects of drug legalisation were systematised and summarised in the light of international experience. The results presented in the final part of the paper include a description of the identified positive and negative factors, based on which partial restrictions on drug trafficking are proposed in the event of their legalisation in a state that currently has strict rules on the handling of narcotic substances (on the example of Ukraine). The results of this study were achieved based on legal analysis and using the forecasting method, which makes the work suitable for future use in conducting research in the field of legislative regulation of drug trafficking.

Results and Discussion

Based on the results of analysing the advantages and disadvantages of legalizing soft drugs in Ukraine, it has been identified several key categories essential for understanding the implications of legalization and state control over drug trafficking. It is crucial to stress that, from a legal perspective, legalization is not a standardized idea. It invariably entails the Ukrainian legislator's decision to partially repeal earlier bans. To put it another way, the relationship here is represented in activities that involve enacting new regulations and, if applicable, repealing existing ones.

Legalisation as a legal phenomenon is the process of conferring legitimacy on certain actions that were not previously regulated by legal mechanisms.[14] In contrast to decriminalisation, legalisation means that they are allowed to be

committed, and the relevant rights are enshrined in the provisions of existing legal acts to make them legal. Decriminalisation, in turn, is accompanied by a reduction of the penalty to the administrative or civil level and provides for the cancellation of negative consequences in the form of a criminal sanction.[15,16] The punishment, as a rule, is transferred to the plane of administrative or other milder liability but is not completely excluded, although it does not lead to a criminal record.[17,18]

Among the member states of the United Nations, there is a growing phenomenon of abuse of gaps in international legal acts in the field of drug trafficking and the use of the terms "legalisation" and "decriminalisation" in their misunderstanding to achieve certain economic effects, since these concepts are not enshrined in the drug conventions. In such cases, it is necessary to distinguish between the state policy aimed at the complete abolition of criminal penalties for personal use of drugs, which is essentially decriminalisation, and the legalisation of usage (use or possession) of internationally controlled substances for purposes other than medical or scientific purposes, and the absence of any type of negative legal consequences. At the same time, the legalisation of drugs is often accompanied by the commercialisation of their trafficking in violation of international conventions. This should be addressed when developing and implementing the state licensing policy on narcotic substances.[7]

The most widespread drugs in Ukraine and abroad are cannabis, opiates, their analogues, amphetamine, methamphetamine, ecstasy and other similar substances of natural and synthetic origin.[19] At the same time, there is no official definition of "soft drugs" in Ukrainian legislation, so it is possible to classify the above substances as a conditionally defined category only based on their chemical properties and impact on physiological processes in the human body but without a formal legal classification with a corresponding name. To determine which substances can be conditionally classified as "soft" drugs, it is necessary to turn to the medical aspect and the existing legal distinction.

Narcotic substances, such as medicines, are chemical compounds that undergo metabolism after producing a therapeutic effect.[20] The intensity of this phenomenon determines the division of substances in medicine into the so-called "soft" and "heavy" categories based on their ability to cause physical dependence and harm to society.[1] The division into these groups, which most people associate with drugs, was enshrined at the state level in the Netherlands in 1976 with the introduction of relevant amendments to the Opium Act.[2] Typically, drugs fall into one of two categories: "soft" or "heavy." Cannabis products (marijuana and hashish) and sedatives and sleeping medicines (Valium, Seresta) fall under the first group. Substances like heroin, cocaine, amphetamines, and ecstasy fall under the second category. Based on the impacts and possible harm connected to each category, this classification represents a regulated differentiation.

In Ukraine, there is a system of classification of narcotic substances into types, which are also allocated to separate lists according to approved tables.[21] From their content, it becomes clear that the grouping system is different from the Dutch model: the prefix "soft" does not appear in Ukrainian drug legislation, and cannabis products are classified as particularly dangerous drugs, the trafficking of which is prohibited. Unlike the Netherlands, where the use and possession of soft drugs in small quantities is not prosecuted under certain conditions, Ukrainian administrative or criminal regulations punish possession depending on the classification of the offence, which is influenced by the amount of the prohibited substance. However, the absence of liability in the Netherlands is due to a special principle that is not formally related to the concept of legalisation and consists of the tolerance of actions that are not permissible under the law under certain conditions, which is partial decriminalisation. The refusal to prosecute for offences related to soft drugs is due to the achievement of a high social goal, which is to ensure public order and much more severe punishment in the case of hard drug offences.[22,23] This explains the possibility of the existence of Dutch coffeeshops ("type of cannabis retail outlet"), which are subject to several requirements and restrictions on licensing, location, advertising, types and volumes of drug products, etc.[21]

The most widely used drug globally is cannabis.[24] This case study can be used to explore the differences in approaches to regulating the circulation of soft drugs in different countries. In 2021, Ukraine took some steps towards legalising medical cannabis. The Verkhovna Rada of Ukraine considered a Law of Ukraine No. 3528-IX "On Amendments to Certain Laws of Ukraine on State Regulation of the Circulation of Plants of the Genus Cannabis for Medical, Industrial Purposes, Scientific and Scientific-Technical Activities to Create Conditions for Expanding Patients Access to the Necessary Treatment"[25] that would have legalised medical cannabis for patients in need of treatment with cannabis-based medicines. The adoption of this law is particularly important due to the critical need for the use of medical cannabis by the military personnel who were seriously injured, lost limbs, or suffered from post-traumatic stress disorder during Russia's large-scale military invasion of Ukraine. Therewith, the production of cannabis for recreational purposes is still prohibited. The draft law amends the Law of Ukraine No. 60/95-VR "On Narcotic Drugs, Psychotropic Substances and Precursors."[26]

The list of narcotic drugs, psychotropic substances and precursors is approved by the Resolution of the Cabinet of Ministers of Ukraine No. 770 "On Approval of the List of Narcotic Drugs, Psychotropic Substances and Precursors."[13] According to this Resolution, drugs are classified according to their degree of danger into four tables. The first table includes the most dangerous substances, the circulation of which is completely prohibited (Table 1). The second table includes substances whose circulation is restricted but permitted

for medical purposes as prescribed by a doctor, in scientific research and veterinary medicine (Table 2). The law also requires the Cabinet of Ministers to move non-medical cannabis from the first table to the second table, which contains less dangerous substances. This creates a certain contradiction: non-medical cannabis moves from the first table to the second, while medical cannabis stays in the first table, with a separate fourth list created for it.

Table 1. Particularly dangerous narcotic drugs, the circulation of which is prohibited.

International unregistered name	Chemical name
Alpha-methylthiofentanyl	*N*-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]-propionanilide
Alpha-methylpentanyl	N-[1-(*a*-methylphenethyl)-4-piperidyl]-propionanilide
Acetyl alpha-methylfentanyl	N-(1-(*a*-methylphenethyl)-4-piperidyl]-acetanilide
Acetorphine	3-o-acetyltetrahydro-7*a*-(1-hydroxy-1-methylbutyl)-6,14-*endo*ethanooripavine
Beta-hydroxy-3-methylpentanyl	*N*-[1-(*b*-hydroxyphenethyl)-3-methyl-4-piperidyl]-propionanilide
Beta-hydroxyphenanyl	*N*-[1-(*b*-hydroxyphenethyl)-4-piperidyl]-propionanilide
Heroin	diacetylmorphine

Source: Resolution of the Cabinet of Ministers of Ukraine No. 770 "On Approval of the List of Narcotic Drugs, Psychotropic Substances and Precursors."[13]

Table 2. Narcotics and plants, the circulation of which is restricted.

International unregistered name	Chemical name
Allylprodyn	3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine
Alfentanil	*N*-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1*H*-tetrazol-1-yl)-ethyl]-4-(methoxymethyl)-4-piperidinyl]-*N*-phenylpropanamide
Alfameprodin	*alpha*-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine
Alfamethadol	*alpha*-6-dimethylamino-4,4-diphenyl-3-heptanol
Alphaprodin	*alpha*-1,3-dimethyl-4-phenyl-4-propionoxypiperidine
Alphaacetylmethadol	*alpha*-3-acetoxy-6-dimethylamino-4,4-diphenylheptane

Source: Resolution of the Cabinet of Ministers of Ukraine No. 770 "On Approval of the List of Narcotic Drugs, Psychotropic Substances and Precursors."[13]

The adopted law stipulates that cannabis for medical purposes in Ukraine can only be grown indoors, i.e., in greenhouses or hotbeds, and not in open fields. A special licence is required for cultivation. Each plant must be assigned a unique number, and the Cabinet of Ministers must create an "electronic accounting system" for plants that will track their transportation and processing. Notably, a person who smuggles across the customs border a narcotic drug purchased for their personal use under a doctor's prescription and in permissible quantities is exempt from criminal liability.

In terms of the content of national legislation, Ukraine has rather strict provisions in terms of punishment for both offences involving the presence of a hard drug substance and those involving less dangerous (in the opinion of a Dutch legislator) "soft" drugs.[27,28] Article 44 of the Code of Ukraine on Administrative Offences[29] and Articles 307 and 309 of the Criminal Code of Ukraine[30] define the following illegal actions with narcotic substances that entail liability: production, acquisition, storage, transportation, and transfer. Production is defined exclusively as a criminal act. Therewith, the distinction between the corpus delicti is determined based on the presence or absence of sale as a purpose, and the provisions of all the above-mentioned codes do not impose liability for consumption. For example, in case of possession for personal use and without the intent to sell cannabis in the amount of 5 to 500 grams, one may receive up to 5 years of imprisonment.[31] Prior to reaching the minimum five-gram threshold for criminal punishment, administrative liability may also be imposed, but not stricter than arrest for 15 days.[27]

With the adoption of the Law of Ukraine No. 3528-IX,[25] the following amendments were made to the Criminal Code of Ukraine.[30] Amendments to Article 310 decriminalised the cultivation of cannabis for medical and scientific purposes, provided that an applicable licence is granted. The cultivation of cannabis without a licence or in violation of the terms of the licence continues to be a criminal offence. Amendments to Article 320 define a separate procedure for the circulation of cannabis-based medicines, including control over their production, storage, and transportation. Violations of these rules, including the illegal production, possession, transportation, or sale of cannabis-based products, continue to be criminalised. These changes are aimed at creating a legal framework to regulate the cultivation and use of cannabis for medical and scientific purposes, while ensuring control over its circulation and preventing abuse.

In 2024, several important legal developments in the legalisation of soft drugs took place around the world. Thus, the United States continues to see significant advances in cannabis legalisation. Currently, 38 states have legalised the medical use of cannabis, while 24 states and Washington, D.C., have authorised its recreational use. The federal decriminalisation of cannabis is

expected to be a key topic, in part due to the possible exemption of cannabis from the Controlled Substances Act.[31] In 2023, the state of Colorado, USA, took a major step towards legalising soft drugs, including psychedelics. Following the passage of Proposition 122,[32] the state began to introduce regulated access to certain psychedelic substances for medicinal purposes. Proposition 122 mandates the establishment of "wellness centres" where adults over the age of 21 can access "natural medicines" such as psilocybin and psilocin for personal use or therapy. The law also allows the cultivation and processing of these substances at home for personal use. The use, possession, transportation, and cultivation of "natural medicines" for personal use has been decriminalised, greatly reducing the level of criminal liability for consumers. By the end of 2024, a full regulatory framework is expected to be in place to govern access to these substances, including licensing of centres and setting standards for "facilitators"—professionals who will assist in the therapy process. The legalisation of psychedelics in Colorado is part of a broader movement in the US that recognises the potential of these substances to treat mental disorders such as depression, post-traumatic stress disorder (PTSD), and anxiety. Colorado's experience could serve as a model for other states and countries considering legalising psychedelics for medical or recreational purposes.

In Europe, Germany specifically, took an important step towards legalising cannabis for recreational use in 2024, which could substantially change the legal landscape not only in this country but also in the European Union. In April 2023, the German government unveiled a plan to legalise cannabis, one of the most progressive steps among the major EU economies.[33] The plan proposes to allow the possession of up to 25 grams of cannabis for personal use and the cultivation of up to three plants per household. Consumption will be permitted in private premises and in certain clubs with special licences. The main goals of this initiative are to reduce the shadow drug market and control the quality of the product, which will help prevent its sale to minors.[34] The government also aims to reduce the criminalisation of cannabis users, which could improve social justice in the country. It is expected that the process of finalising the legislation will be completed in 2024, after which its implementation will begin. Notably, this process will be gradual, with ongoing monitoring and evaluation of the impact on society, the economy, and public health.

In 2023, Thailand became the first country in Asia to legalise cannabis. This event caused a strong resonance as the region is known for its strict drug laws. Legalisation was partly aimed at stimulating the country's economy by developing a new industry and attracting tourists. In Thailand, cannabis legalisation has undergone several stages. Initially, in 2018, the country permitted the use of cannabis for medical purposes. However, in 2023, the legislation was expanded to allow home cultivation of cannabis for personal and recreational use.[35] To grow and sell cannabis in Thailand legally, one must obtain a licence

from the government, which enables the state to control the quality of the product and prevent it from reaching minors.[36] The legalisation of cannabis has also become an essential factor in the development of a new industry focused on exporting products and attracting investment. The sector is expected to bring considerable revenues to the country's economy, creating new jobs and raising living standards.

Legalisation has provoked a variety of reactions. Proponents believe it will contribute to medical research and economic growth, while critics have expressed concern about the possible increase in drug abuse and social problems associated with uncontrolled cannabis use. Below is a chart with a list of countries that have decriminalised cannabis possession within the limits set by local regulations (Figure 1).

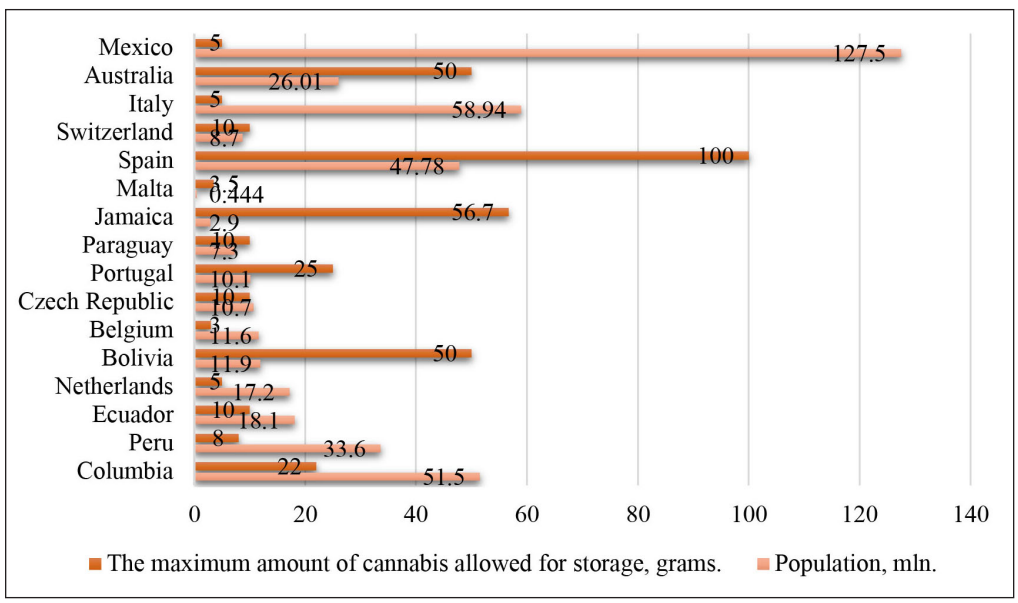

Figure 1. Decriminalisation of cannabis possession, 2023.
Source: compiled by the author based on.[37]

The data shows the heterogeneity and independence of each state's approaches to determining the limits of permitted use of the drug, which indicates a different degree of decriminalisation.

The legalisation of soft drug use in its legal sense can be seen in the case of Uruguay, Canada, South Africa and Georgia, where recreational cannabis use is allowed. The legalisation of recreational cannabis in Canada took place with the entry into force of the Cannabis Act of Canada.[38] According to Art. 7 of the Cannabis Act of Canada,[38] its purpose is to protect the health of young people, reduce profits from the illicit trade in soft drugs, reduce the burden on the jus-

tice system, control the quality of raw materials and inform society about the health risks of cannabis use. From the Canadian legislator's perspective, legalisation is seen as a reasonable social and health policy. However, the potential danger of promoting cannabis use among young people due to the lack of age restrictions on marketing in this area is a concern. Compliance with the rules for covering soft drugs is also important in terms of reaching an audience not only within the country but also addressing the presence of users with access to social media outside the country.[3]

Uruguay was the first country to officially legalise the use of soft drugs. The Law of Uruguay No. 19.172 "Marijuana and Its Derivative"[39] regulates the production, marketing and use of cannabis, and provides for measures to disseminate information and education to prevent its use. According to Art. 2 of this document, the state has assumed control over the regulation of the import, export, planting, cultivation, harvesting, production, acquisition in any capacity, storage, marketing and distribution of cannabis and its derivatives or hemp, where appropriate, through legally authorised institutions.

In South Africa, a Constitutional Court[40] decision allowed the use of cannabis for personal recreational purposes. According to the requirements of the case law, in 2020, the South African legislator introduced the Cannabis for Private Purposes Bill,[41] which is currently the subject of public discussion and is aimed at finalising its content in terms of regulating commercial activities with recreational cannabis, conducting transactions with it for religious and cultural purposes by members of relevant organisations, as well as to consolidate the provisions on respect for adults' privacy in terms of the use of cannabis for medical purposes.[42]

The actual legalisation of cannabis uses in Georgia (with the exception of public and workplaces) occurred with the adoption of several decisions by the Constitutional Court of Georgia, which declared unconstitutional the provisions on prosecution for the use of soft drugs:

- imprisonment for the acquisition and possession of dried marijuana for personal use was declared unconstitutional in 2015 (in the case of substances up to 70 grams);[43]
- criminal liability for the use of cannabis was abolished, and in 2017, the provision requiring a doctor's prescription was removed;[44]
- the administrative sanction for the use of marijuana without a doctor's prescription or a prescription was cancelled in 2018;[45]
- in 2020, the criminal penalty of imprisonment for 5 to 8 years for the illegal acquisition and storage of drugs in amounts unsuitable for consumption was also cancelled.[46]

Analysing the prospects for legalising the use of soft drugs in Ukraine, it is possible to predict the emergence of issues and violations in the regulation of advertising activities related to the dissemination of information regarding the

properties of currently prohibited substances. At the same time, in the case of legalisation, the regulatory framework should cover an exhaustive list of permitted actions for the advertising of drugs or completely prohibit their public commercial offer.

Official data indicate a very high level of drug use among Ukrainian youth and a low age threshold for the first use of illicit drugs (90% of drug users in Ukraine are under 25 years old, the average age of first use is between 13 and 15 years old). The social and economic problems in the country that contribute to this include a decline in the quality of life, economic instability, unemployment, an increase in the overall crime rate and alcoholism in families.[19,47]

The experience of the Netherlands shows that most cannabis users are in the 15-34 age group, similar to cocaine, amphetamines and methylenedioxymethamphetamine users.[48] The most recent data on reported drug-related crimes in Amsterdam (2010–2022) are shown in Figure 2.

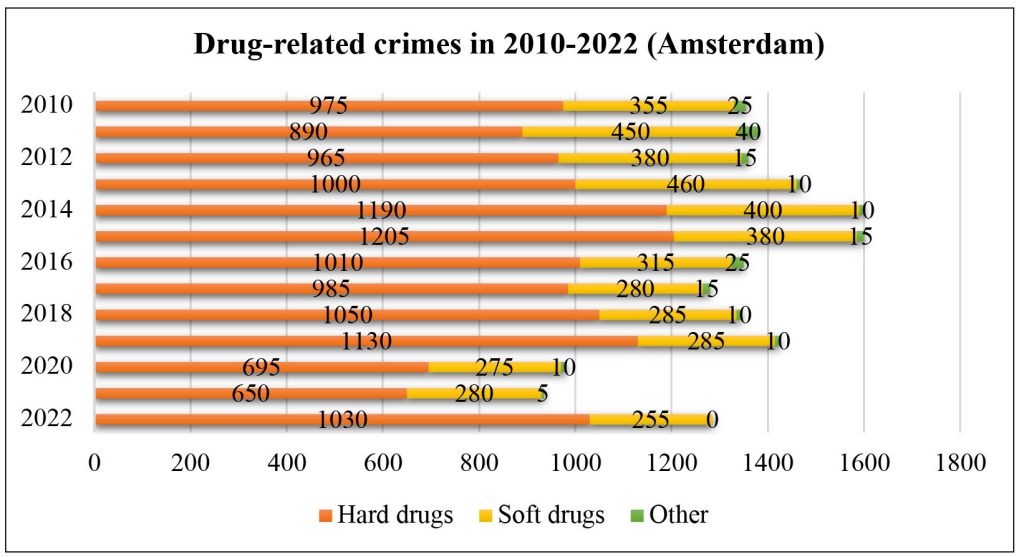

Figure 2. Statistics of registered drug-related crimes for 2010-2022 in the city of Amsterdam (the Netherlands).

Source: compiled by the author based on.[49]

The legalisation of soft drugs in the Netherlands did not improve the situation, as the overall level of drug addicts did not decrease.[50] According to the figures for previous periods, from 2008-2017, the number of prescription opioid users doubled from 4109 to 7489 people per 100,000 population, especially due to the increase in the number of oxycodone users (from 574 to 2568 people per 100,000 population during the period). Deaths from opioid dependence, compared to similar figures in 2008-2014, have increased as of 2017 (65

deaths were recorded, when previously only 21 deaths per 100,000 people were recorded).[51] According to the most recent data as of 2024, the total number of fatalities from drug use of all types also increased in the Netherlands between 2006 and 2021, as can be seen in the following graph (Figure 3).

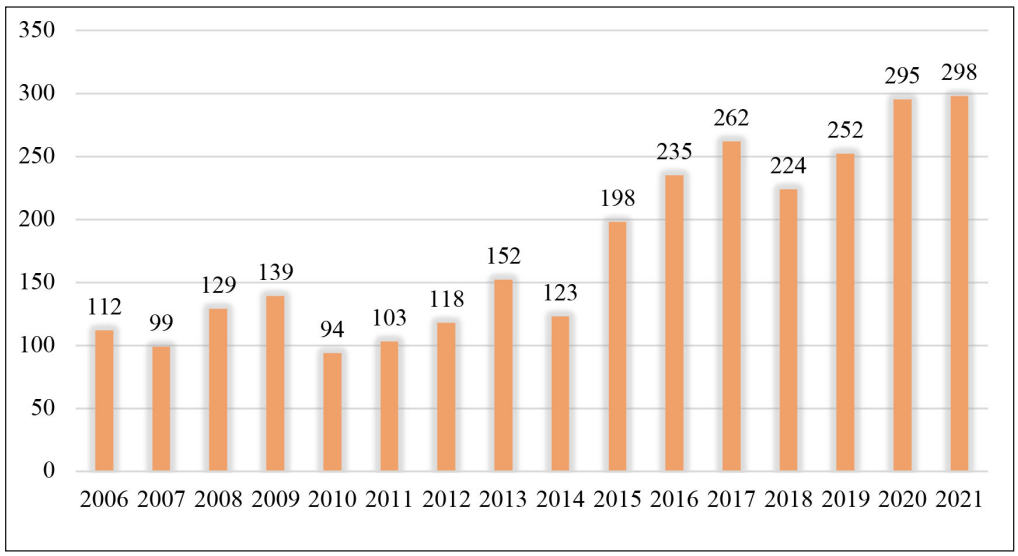

Figure 3. Total number of drug-related deaths in the Netherlands from 2006 to 2021.

Source: compiled by the author based on.[52]

The effect was positive in that it simplified control of the population that uses drugs, but the total number of users (including adolescents) increased slightly. According to the Dutch Central Bureau of Statistics,[53] since 2014, the use of cannabis among people aged 12 and older has increased by 3.5% as of 2021, and other drugs (amphetamine, ecstasy, cocaine, heroin, methadone, etc.) by 1.6%. According to the survey, almost a quarter of the population over the age of 15 (23.4%) reported having witnessed drug use or trafficking in their neighbourhood.[54] Given the above, legalisation in Ukraine may lead to additional popularisation of soft drugs, given the existing availability and the prospect of introducing advertising mechanisms that will help attract a new audience among young people. Under such conditions, the risk of a certain percentage of users turning to harder drugs will increase.

Research suggests that the correlation between marijuana use and the transition to harder drugs is not fully proven. On the contrary, the prohibition of soft drugs is possibly a cause for replacing them with harder drugs. Therefore, the state policy of criminalising cannabis use, according to this point of view, causes the opposite effect.[4] Despite the existence of these associations with the use of drugs with different effects on the body, there is no convincing

evidence that soft drugs are "transient."[5] At the same time, researchers note that a combination of genetic and environmental factors increases the likelihood of a risk of further transition to hard drugs, especially if drug use begins in adolescence.[4,6] From a medical point of view, systematic drug use causes poisoning of the body, which leads to dependence and exhaustion. Abstinence from drug use leads to a severe psychophysiological state, so reducing the age of drug users is a significant problem that requires active counteraction at both the national and international levels.[55,56]

Given the practice of police in the United States of America, after the legalisation of soft drugs in some administrative units of the country, there are trends of widespread introduction of cannabis to young people. This is combined with the reluctance of law enforcement agencies to consider offences in this regard due to age-related peculiarities and attempts to apply educational influence at the level of educational institutions instead of initiating court proceedings involving a minor offender. Police and prosecutors in the United States pay less attention to offences involving soft drugs, which leads to a decrease in their total number due to the so-called "deprioritisation." This results in no impact of cannabis legalisation on the number of recorded drug trafficking and related offences. However, in practice, cannabis legalisation has had an impact on road safety, as law enforcement officials claim that there has been an increase in the number of cases of driving under the influence of drugs among American drivers.[57,58] The Dutch police have also noted a significant increase in the number of cases of driving under the influence of drugs: while in 2017, there were 1,834 cases of these offences, in 2021, more than 13,000 police reports were filed. In the first two months of 2022, 2,650 drivers were arrested for driving under the influence of drugs, which indicates an upward trend in these offences.[59]

From a financial point of view, the effect of regulating the circulation of soft drugs at the state level as a result of the implementation of modern licensing mechanisms may prove to be economically feasible. Replenishment of the budget through revenues from the legal drug trade will help improve the crime situation. Criminal prosecution of marijuana sales reduces demand for marijuana, which leads to higher prices, which leads to increased financing of the illegal drug trade in terms of drug proceeds.[60] Tax revenues from drug trafficking can be used to develop socially important areas that are essential for the development of society but are not attractive in terms of public spending on their support (education, rehabilitation, etc.).[61] This is the principle behind the system of saving and earning money from marijuana sales in states where legalisation is in place.[62,63]

Considering the aspects of the possible legalisation of soft drugs at the state level, opponents of the easing of prohibitions emphasise the negative

consequences in the form of an increase in the number of cases of teenage drug addiction, an increase in the overall crime rate and an increase in the number of road accidents. Such warnings seem understandable in the context of the commercialisation of the soft drug market, but there is currently no sufficient evidence of the relationship between decriminalisation and consumption, crime and road safety. Given the absence of uniform rules at the international level for determining the limits of the free use of soft drugs for recreational purposes, all the arguments in favour and against their legalisation or decriminalisation show a variety of approaches to this issue without a commonly accepted one for most countries.

Conclusions

Based on the study's findings, it has been identified the salient characteristics that set "legalization" and "decriminalization" apart, highlighting their significance in establishing the legal framework that regulates the use of soft substances. There is presently no "soft drug" category in Ukrainian law. Rather, national regulations categorize medications that are substantially less toxic in other nations as extremely dangerous and forbid their distribution. It would be wise to progressively introduce the use of soft drugs with a probationary term to monitor results and resolve unforeseen repercussions, given the traditionally unfavorable attitude towards drug use that is ingrained in Ukrainian legislation.

A well-thought-out soft drug tax policy might reduce the illegal drug trade and greatly increase the state budget. However, enacting laws to combat drug trafficking must also include steps to stop drug use among teenagers from spreading, like stringent advertising limits and a prohibition on drivers using cannabis to reduce the danger of traffic accidents.

Dutch law is the source of the widely accepted definition of soft drugs. Ukraine can learn a lot from the varied approaches to cannabis legalization taken by the Netherlands, Germany, USA, and Thailand. For instance, in order to curb criminal markets and protect public safety, Germany intends to legalize cannabis for recreational use in 2024 under stringent regulatory guidelines. In order to safeguard the public's health, Colorado legalized cannabis in 2012 and established strong quality control and licensing procedures. Thailand's 2023 cannabis laws prioritize medical use and product quality, lowering trafficking dangers and promoting economic growth. Law No. 3528-IX, which was just passed in Ukraine, legalizes cannabis for medical use but prohibits its recreational use while the Cabinet of Ministers considers additional rules.

But given the present harsh punishments for drug-related offenses in Ukraine and the ease of access to drugs, there are worries that legalizing cannabis for recreational use won't have a big social impact. Instead, similar to problems like underage drinking, it might encourage the emergence of a new

drug-dependent community, especially among teenagers. A number of legislative changes are required in order to properly discuss legalizing soft drugs for recreational use in Ukraine. These should mandate educational efforts to educate youth about the dangers of drug use during adolescence while attempting to strike a balance between public health and economic interests.

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Data Availability: The author confirms that the data supporting the findings of this study are available in the article.

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Reconsidering the Ethical Framework of DMV-based First-Person Authorization for Organ Donation

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ABSTRACT: This article critically examines the ethical dimensions of utilizing Department of Motor Vehicles (DMV)-based First Person Authorization (FPA) for organ donation. While ostensibly designed to uphold patient autonomy, DMV-based FPA raises significant ethical concerns due to its lack of informed consent and limited impact on organ donation rates. Drawing on principles of autonomy, informed consent, and medical ethics, this article argues for a reevaluation of current practices and proposes alternative approaches that prioritize genuine informed decision-making.

Definitions:

Moral Patient: One that possesses the capacity to be wronged or righted.[1]

Moral Agent: One that possesses the ability to do right and wrong.[1]

Moral Status: One that matters morally for its own sake.[2]

Morally Salient: The extent to which one's actions are morally noticeable or relevant.[54]

Authorization: Permission for something to happen.[53]

Legitimate Authorization: Authorization with sufficient reason to believe the authorization is justified and ought to be abided by.

Mere Consent: Consent that does not fulfil the standards of informed consent.

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Moral Status of Dead Bodies

To begin a discussion about ethical action toward dead bodies or the deceased, it is important to establish whether a dead body has moral status and can be a moral patient: if a dead body is not a moral patient (in the same way many other inanimate objects are not considered moral patients), then wrongs cannot be done to them.[1] While the moral status of a dead body has not been universally agreed upon, there are numerous laws, ethics publications, and social practices that provide evidence dead bodies are and should be treated as moral patients.[3-6]

Examples of legal and social proscriptions around the world include laws and taboos against necrophilia, cannibalism, and desecration of graves.[7-10] These actions are commonly seen as wrong, not just because they are upsetting to observers or the living who care about the dead body, but because these actions constitute a wrong done to the dead body because the dead body possesses some intrinsic quality.[11-13] Examples of arguments put forward to ground dead bodies' moral status as moral patients are as follow:

1) The dead body possesses dignity as a result of its previous status as a living human being who possessed dignity that is not lost upon death.[11,14-16]
2) How a dead body is treated plays an important role in the afterlife of a deceased individual in many religious traditions through time.[17-21]
3) While the dead body does not have interests, the living person did, and currently living people have an obligation to respect those interests after death.[22-23]

A powerful literary example comes from the ancient Greek play *Antigone*, in which a young girl (Antigone) defies a decree to leave her deceased brother's body unburied and performs a rudimentary burial.[24] Antigone is willing to pay the ultimate price (her own life) to perform what she believes to be her duty to enact certain post-mortem rituals on her deceased brother's corpse.[24] The reader of this play is not confused why Antigone would be willing to sacrifice her own life to bury an inanimate object (as one might be if she sacrificed herself to bury a rock). In fact, the play turns on the idea the audience accepts the premise that certain respects ought to be paid to the deceased. This play's existence and continued relevance seems to indicate the intuitive pull many feel that dead bodies deserve a certain degree of consideration.

Further, even if a dead body does not have moral status, committing certain actions toward a dead body may be wrong if those actions cause indirect harm to another being with moral status who has an interest in a particular dead body.[25] This may be most clearly recognized in the ethics of destroying another's property.[26-27] One example might be when one child destroys a toy belonging to another child. Many parents would recognize a wrong done, and the first child would likely be instructed to apologize to the second child.

However, the first child is not instructed to apologize to the toy, even though the toy was the thing that was destroyed. While a dead body may not be considered property, certain individuals (such as family members) may have a legitimate interest in the dead body such that performing certain acts to a dead body may constitute a wrong done to an individual with an interest in the body.[25]

What Dead Bodies are Owed

While dead bodies might be moral patients themselves or deserving of moral consideration as meaningful objects to others who are moral patients, it is not immediately clear what dead bodies are owed or what limits ought to exist for conduct against dead bodies.[3] Beyond acts that are categorically proscribed (necrophilia), there may be acts that can be done to a corpse only if the act is in accord with the wishes the deceased individual had when they were living. Some examples include practicing medical procedures on dead bodies, conducting research on dead bodies, and the retention of organs post mortem.[5, 31-39] These acts, like those that are categorically proscribed, use the dead body as a means to an end; however, unlike acts that are categorically proscribed, these acts also offer an important good of some kind (fulfilling a pre-mortem wish for parenthood and satisfaction of a spouse's goals, training healthcare providers, furthering scientific knowledge, providing training tools). While the goods generated are important, they are not so important that one might rightly obtain the good without knowledge that doing so is in accord with the patient's wishes.[31-39]

Likewise, while respecting the known wishes of the deceased is recognized to be ethically important, it is not so important that the known wishes of the deceased should be categorically respected.[40] Surely there are cases in which respecting the wishes of the deceased is not morally obligatory, such as when the wish cannot be reasonably fulfilled, the cost of fulfilling the wish is too high, or a significantly important harm is done or benefit failed to be realized as a result of fulfilling the wish. An example might be if the deceased requested their ashes by spread in an unauthorized location or a unreasonably large donation be made in their name. As such, when considering whether an act can be done without knowledge of the deceased's wishes, one must know whether there are ethically compelling reasons why the act can be done with knowledge it is in accord with the deceased's wishes.[40]

An important question to answer is how one might know what a deceased person's wishes are, if the person is deceased and, as a result, unable to communicate them? For adults, as a general rule of thumb in medicine, we rely on informed consent provided by a capacitated patient or, in the case of an incapacitated patient, informed consent provided by a surrogate decision-maker who uses the substituted judgement standard.[41-45] Particularly important in

informed consent is the informed aspect, with requirements that the patient be told the diagnosis, the reason for the recommended treatment, risks, benefits, burdens, and alternatives (including no treatment).[41] Disclosing this information is important because a decision made by the patient that is not fulling informed may not accurately reflect the patient's wishes.[46-47] As such, mere consent cannot be considered a reliable indicator of patient preferences as any decision made under mere consent is uninformed of potentially relevant information. While more challenging and less concordant with patient wishes, we still attempt to honor patient wishes when they lack decision making capacity all the way to and through end-of-life through reliance on substituted judgment and completion of advance care planning document.[45, 48-50] While imperfect, these may be the best tools we have to attempt to respect the wishes of incapacitated and deceased patient's wishes.[50]

Donor Wishes and First-Person Authorization

Society largely recognizes the importance of following patient wishes as it relates to organ donation as well, so much so First-Person Authorization (FPA) is considered legally binding, as set out in the Uniform Anatomical Gift Act, from which much of so called 'gift law' is derived.[51-52, 75] Proponents of FPA argue FPA respects people's wishes in that it allows people to make an autonomous pre-mortem decision regarding their organ use post-mortem, with the understanding that informed consent is no longer required once an individual is deceased and mere authorization is sufficient.[55-56] Additionally, the Organ Procurement and Transplantation Network (OPTN) has updated their glossary, shifting from the term "first person authorization" to "first person consent," (FPC) possibly emphasizing the fact that the individual is consenting to a medical procedure as the term 'consent' is the one typically used in medical settings when discussing authorization for a medical procedure.[57-58] However, Uninformed FPA/FPC (such as the typical FPA done at the DMV) is not informed consent as little information is provided regarding the procedure or alternatives beyond asking the individual if they would like to be a registered donor. The new verbiage of FPC may acknowledge this as well, as it is merely "first-person consent", and not first-person informed consent. If this correct, it raises the question of why mere consent is sufficient for authorizing a medical procedure, but informed consent is not necessary.

As it relates to other medical interventions and research, some have argued that mere consent is ethically permissible in certain circumstances based on the certain features (or lack of those features) that may be considered morally salient (such as risk, pain, and invasiveness).[59-61] Further, it is largely understood in the law that what should be disclosed is based on what information is material to the patient, and not just the information the clinician believes to be important.[62-63] From these premises, one may conclude that informed con-

sent is required when aspects of the medical procedure would be material to a reasonable person, but mere consent is sufficient when all aspects of a medical procedure are not material to a reasonable person. If this standard applies for consent involving living patients and some post-mortem procedures (such as certain autopsies, practice procedures, and organ retention), then the next question becomes does organ procurement for organ donation have morally salient features such that informed consent is ethically obligatory or are there reasons to believe mere consent is sufficient?[31-39]

To begin, it is important to understand whether there are features of the procedures of organ procurement and transplant that may be morally salient. A few poignant examples supporting the view that there are morally salient aspects related to organ donation include the ethics debate surrounding brain death, normothermic regional perfusion (NRP), and premortem interventions.[64-68] Additionally, as any clinician who has encountered a family who refutes the concept of brain death or expresses unwillingness to allow premortem interventions to optimize organ donation can attest, these concepts are far from settled in everyone's mind. As such, we should recognize that certain aspects of the organ donation process are ethically controversial and may be morally salient to some patients and there is not clear consensus on what role surrogate decision makers should play regarding donation in cases where FPA has been provided.[73] Given the extent of the debate surrounding these topics, it is clear organ donation involves aspects arguably at least as morally salient as other postmortem interventions that do require informed consent.

That being said, even if there are morally salient aspects of organ donation, it is still possible there are other counterbalancing facts that may make organ procurement with mere consent sufficient. The primary condition often proposed would be if DMV-based FPA increased the number of organ donations so significantly, that the good done removed the need for informed consent that may otherwise be necessary for a controversial medical intervention about which reasonable people may disagree.[51] However, DMV-based FPA has not been shown to increase the rate of organ donation or transplant.[69]

While the exact reasons for this lack of increase in the number of donors remain unclear, the absence of evidence supporting a significant increase in donations undermines a central argument for using DMV-based FPA as legitimate authorization for organ donation. This finding suggests that relying on FPA as a justification for using mere consent instead of informed consent is not empirically grounded. Consequently, the use of DMV-based FPA must be justified on other empirical or ethical grounds, considering that one of its primary purported benefits has not been shown to be true.[69] The ethical implications are significant, as the justification for bypassing informed consent cannot rest on an assumed increase in organ donations that has not convincingly been shown to occur. Further, the burden of proof for benefit should lie on those

who support the use of a controversial medical procedure without informed consent as this represents a diversion from typical ethical medical practice.

Conclusion

Reviewing the primary arguments for why Uninformed FPA is ethically sufficient, many have argued that:

1) Dead people do not have interests; therefore, they are not moral patients, and society does not have obligations to obtain informed consent for intervention on non-moral patient.[70]
2) Using DMV-based FPA as authorization for organ donation, regardless of surrogate decision maker dissent, respects patient wishes, and is therefore legitimate.[72,74]
3) DMV-based FPA increases the supply of organ; therefore, the good achieved through the use of DMV-based FPA is sufficiently valuable that the otherwise typical requirements for informed consent prior to medical procedures are not applicable.[51]

In this article, I have attempted to address these arguments by demonstrating:

1) We commonly recognize dead people as having moral status, either as moral patients or as meaningful objects important to others with moral status, as evidenced by how we treat dead bodies and the proscriptions against certain acts.
2) Mere consent may be sufficient for uncontroversial procedures, but informed consent is required for procedures with morally salient features about which reasonable people may disagree, as evidenced by the requirement for informed consent for other controversial post-mortem procedures. Further, informed consent is more likely to reflect the person's actual wishes as a decision made under full information is more likely to accurately reflect a person's wishes than one made without knowledge of potentially morally salient features.
3) There is no compelling evidence that DMV-based FPA increases the supply of organs and some evidence that it fails to increase the supply of organs and therefore fails to realize the sought after external benefit. Further, the burden of proof lies with those advocating a departure from typical ethical medical practice.

Given that dead bodies are worthy of moral consideration, society accepts the need for informed consent for ethically controversial post-mortem medical interventions, the procedure of organ donation is ethically controversial amongst reasonable people, and there is no evidence that Uninformed FPA increases the rate of organ donation, one may conclude that the use of Uninformed FPA as authorization for organ donation is not consistent with current ethical practice in medicine and there is no compelling reason to violate the ethical standard requiring informed consent for medical procedure. Therefore, Uninformed FPA is not ethically sufficient to proceed with organ procurement

without informed consent from the donor prior to loss of capacity or a surrogate decision maker after the donor loses capacity.

With these issues discussed, DMV-based uninformed FPA should be advisory to surrogate decision-makers, not legally binding. FPA should only be legally binding if the prospective donor was informed of all morally salient features of organ donation and agreed to the procedure while capacitated. This could be done at the DMV, but only if there is someone with sufficient medical expertise to discuss the morally salient features with the prospective donor; otherwise, information sharing regarding medical procedures should be reserved for a more suitable venue, such as a doctor's office. FPA can be a useful and ethically supportable tool to encourage organ donation and allow people to make decisions about their bodies, but only if the individual is doing so with full knowledge of the morally salient features.

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Verbatim

Committee Opinion 12 - Ethical Treatment of Human Embryos*

> It is in Man's power to treat himself as a mere 'natural object' and his own judgments of value as raw material for scientific manipulation to alter at will. The objection to his doing so does not lie in the fact that this point of view (like one's first day in a dissecting room) is painful and shocking till we grow used to it. The pain and the shock are at most a warning and a symptom. The real objection is that if man chooses to treat himself as raw material, raw material he will be: not raw material to be manipulated, as he fondly imagined, by himself, but by mere appetite, that is, mere Nature, in the person of his dehumanized Conditioners."-CS Lewis[1]

Each of us began our existence as a human embryo, and from our embryonic beginnings, we experience continuous development and differentiation throughout life.[2] As medical professionals who live out the Hippocratic Oath[3], we have a compelling responsibility to the human beings under our care. As medical professionals in Obstetrics and Gynecology, we have a long history of recognizing that both the pregnant mother and the human being in her womb are our patients. "Through quality perinatal care, the specialty promotes the health and well-being of the pregnant woman and her fetus."[4] We have the privilege and responsibility to care for both of them.

Our responsibility to care for our youngest patients begins when a new human organism begins. Thus, the key scientific question addressed by this Committee Opinion is whether or not the embryo is a human organism, i.e., a human being. The answer to this question has significant implications for the practice of Assisted Reproductive Technology (ART), especially In-Vitro Fertilization (IVF), and also for the creation and use of human embryos for research, as exemplified by the recent proposal introduced in the UK Parliament for the creation of human embryos in "industrial quantities" for experimentation.[5] This Committee Opinion will explore the scientific

* American Association of Pro-life Obstetricians and Gynecologists.

evidence surrounding the beginning of a human organism/human being and then the necessary implications of this information for the ethical treatment of embryos in both research and IVF.

What Kind of an Entity is the Human Embryo in Vivo?

Embryos in vivo start as the product of sperm-egg membrane fusion in the mother's fallopian tube. Sperm-egg membrane fusion results in the creation of a zygote, which is a one-celled embryo. Dr. Maureen Condic has published the key scientific considerations that bear on the specific question of the kind of entity produced by sperm-egg membrane fusion. The two key questions that must be considered are 1) When is a new cell formed that is distinct from the sperm or the egg? and 2) Is the resulting new cell a human organism (i.e., a new human being)? Condic answers these questions as follows:

> Based on universally accepted scientific criteria, a new cell, the human zygote, comes into existence at the moment of sperm-egg fusion, an event that occurs in less than a second. Upon formation, the zygote immediately initiates a complex sequence of events that establish the molecular conditions required for continued embryonic development. The behavior of the zygote is radically unlike that of either sperm or egg separately and is characteristic of a human organism. Thus, the scientific evidence supports the conclusion that a zygote is a human organism and that the life of a new human being commences at a scientifically well defined "moment of conception." This conclusion is objective, consistent with the factual evidence, and independent of any specific ethical, moral, political, or religious view of human life or of human embryos.[2]

Elsewhere, Condic states:

> ... the embryo acts in a coordinated, organismal manner to produce and to regulate its own development. All of the actions of the embryo are directed toward producing the structures and relationships required for the ongoing life and health of the embryo as a whole. At no time does the embryo even remotely resemble a mere human cell or collection of human cells.[6]

It is clear that the defining feature of an embryo is organized self-directed growth and development, which begins at the moment of sperm-egg membrane fusion. The zygote clearly exhibits subsequent changes in the metabolic activity and actions that mark the zygote as a human organism, distinct from either the oocyte or sperm. He or she is an organism at the zygote stage. This human being has one continuous biological existence throughout his or her developmental stages, from zygote through the stages of embryo, fetus, newborn, toddler, child, teen, adult, and aged adult, until the life of that human being ends in death. Human beings have different lifespans, some spanning

decades, some spanning years or days, and some spanning seconds or minutes in the embryonic stage. The age of a human being is not determinative of his or her value.

Sperm-Egg Fusion in Vivo does not Always Result in an Embryo

Although some products of sperm-egg fusion may be embryos with a life-limiting condition and some gametes may be deficient in ways that prevent an embryo from forming upon the fusion of the sperm and egg membranes, sperm-egg membrane fusion is clearly the point at which human life in vivo naturally begins. Again, while nutrients are required, this new organism is self-integrated and oriented toward its own survival. The same is true for every other species that begins with a fusion of male and female gametes.

Deficiencies in either sperm or egg may result in an inability to form an organism at sperm-egg fusion. One example in vivo is the case of a complete hydatidiform mole (CHM). CHM forms when only paternal DNA is present to bind to an egg devoid of a nucleus. "In complete moles, the karyotype is 46XX 90% of the time and 46XY 10% of the time. It arises when an enucleated egg is fertilized either by two sperms or by a haploid sperm that then duplicates and therefore, only paternal DNA is expressed."[7] The CHM does not have organized self-directed growth and universally forms a disorganized tumor. Therefore, a CHM is not an embryo.

At this time, we do not have the ability to detect other examples of sperm-egg membrane fusion in vivo that do not meet the criteria of an organism. Detection of such entities would require a marker to detect sperm-egg membrane fusion in vivo, which currently is unknown. We also do not know the rate of in vivo formation of embryos with life-limiting conditions that do not continue to implantation. To determine the rate of in vivo formation of embryos with a life-limiting condition will require the development of a fertilization marker and application of this marker to normal sexually active females in the late luteal phase, compared to the subsequent pregnancy rate in that population.

Sperm-Egg Fusion in Vitro does not Always Result in an Embryo

In vitro fertilization allows for the direct observation of the initial stages of embryo development, albeit in an environment that does not entirely mimic the conditions in vivo, which may affect the results observed.

Estimates based on recent data show that during IVF cycles, approximately 70-79% of oocytes exposed to sperm form normal zygotes (the fertilization rate, as evidenced by the formation of two pronuclei, i.e., "2PN embryos" as shown in Figure 1, Day 1), while some older data show a fertilization rate of 53-81%.[8, 9]

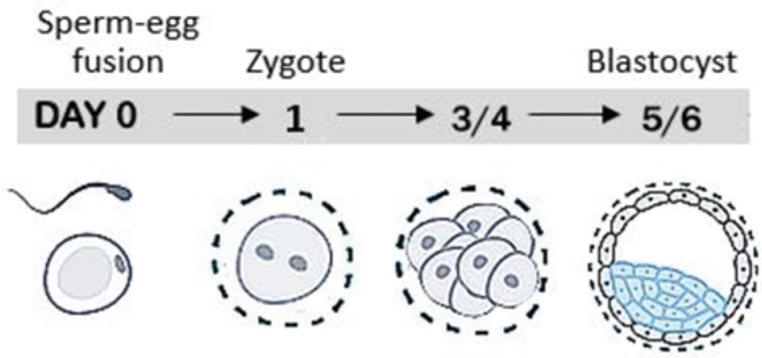

Figure 1 – Day 0 to Day 6

AAPLOG affirms the objective biological fact stated earlier that the product of sperm-egg membrane fusion is a human embryo in the zygote stage of human life:

> the scientific evidence supports the conclusion that a zygote is a human organism and that the life of a new human being commences at a scientifically well defined "moment of conception." This conclusion is objective, consistent with the factual evidence, and independent of any specific ethical, moral, political, or religious view of human life or of human embryos.[2]

We recognize that roughly a third of these embryos formed in vitro will have life-limiting conditions where the zygote initiates development, but development arrests. According to Romanski et al., of the entities formed at sperm-egg membrane fusion (zygote) in vitro, approximately one-third will not continue development to the point of blastocyst formation.[10] However, a short duration of embryo survival does not mean that the embryo did not exist, just as a short duration of human life at any stage does not mean that a human being did not exist.

Some pro-life medical professionals hold an alternative view that after sperm-egg membrane fusion, the entity formed must demonstrate continued organized development to be recognized as a human being. This view would state that some of the products of sperm-egg membrane fusion are non-embryos and that an embryo cannot be definitively distinguished from a non-embryo until that non-embryo ceases to exhibit continued organized growth toward the functioning of the organism as a whole.

In this alternative view, it is recognized that we have no means of distinguishing non-embryos from embryos at the zygote stage and no means at that stage of distinguishing non-embryos from embryos with a life-limiting genetic, epigenetic, or physiological limitation that does not allow for continued embryo survival.

When there is uncertainty as to whether or not a human embryo has been formed, we ought to err on the side of caution. This ethical principle is routine-

ly applied in other situations where innocent human life may be at risk, such as hunting. For example, if deer hunters see movement in the bushes, they are compelled not to shoot until they determine definitively that the movement is from a deer, not a human.

With either viewpoint, we are compelled to treat all of the products of sperm-egg membrane fusion as human embryos until it becomes clear that they are not continuing to exist as living embryos, either through lack of development, cessation of development, or chaotic development.

From either viewpoint, however, we can say with certainty that when a human-derived organism shows development consistent with the corresponding stage of human embryonic life, then that entity meets the criteria for being a human embryo, even if that embryo cannot continue development due to genetic, epigenetic, or physiological limitations.

Embryos Can Be Formed in Vitro by Means Other Than Sperm-Egg Fusion.

In vivo (under natural conditions), sperm-egg fusion is the point of initiation of the human zygote, a new human being. However, in vitro, an embryo can also be formed by other mechanisms, which result in an entity with the structure and function of a normal embryo at an equivalent stage of development, as exemplified by human embryo models made from stem cells, which will be discussed below. In this case, in which there is no sperm-egg fusion, it is the continued organized functioning of the human organism toward the well-being of the human organism that confirms what is and is not a human embryo.

Ethical Treatment of Human Embryos in Research

Research with embryonic stem cells has produced a variety of entities, including human embryos, by means which bypass sperm-egg fusion. Some of those entities are human embryos because they fulfill the criteria of a human organism: "*The critical difference between a collection of cells and a living organism is the ability of an organism to act in a coordinated manner for the continued health and maintenance of the body as a whole.*"[11] When a human-derived entity exhibits the ability of an organism to act in a coordinated manner for the continued health and maintenance of the body as a whole, that entity is a human organism, i.e., a human being.

What, then, are the responsibilities of the scientific and medical communities toward respecting the human rights of these vulnerable human beings in research?

The ethical responsibilities of human subject researchers are drawn from and mirror the ethical responsibilities of medical professionals toward their patients. There are three international consensus documents addressing the ethical responsibilities of medical professionals and researchers toward human subjects:

a) The Hippocratic Oath, which formed the basis of medical ethics
b) The Helsinki Declaration of the World Medical Association and
c) The Belmont Report, which was formulated in the US after the atrocities committed by the scientific and medical communities in WWII.

We briefly examine the pertinent principles here:

The Hippocratic Oath[3]

The Hippocratic Oath states, "I will always seek the physical and emotional well-being of my patients, according to my best ability and judgment, being careful to cause no intentional harm."

In recognition of our shared humanity, the Hippocratic Oath calls both medical professionals and human subject researchers to hold the well-being of the human subject paramount. In research, this means not conducting experiments on human subjects, including human embryos, which could possibly lead to their death or harm. It also means assigning proxy decision-makers charged with defending the life and well-being of vulnerable human beings in cases where informed consent from the subject cannot take place.

The Helsinki Declaration of the World Medical Association[12]

The following are excerpts from the Helsinki Declaration, which discuss medical research on human subjects [numbers in brackets represent the page of the Helsinki Declaration where the quote is found]

> The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. [page 1]

> Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles. [page 2]

> While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects. [page 8]

> It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. [page 9]

> Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects. [page 16]

> Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed. [page 18]

The Helsinki Document also directly addresses research involving vulnerable groups and individuals:

> Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection. [page 19]

> Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research. [page 20]

> For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden. [page 28]`

The Belmont Report[13] *(National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research)*

The Belmont report also discusses medical research on human subjects:

> Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.
>
> 1. Respect for Persons. — Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.... Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated. Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; ... The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit.

2. Beneficence. — Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being... Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others.

3. Justice. — Who ought to receive the benefits of research and bear its burdens?... the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all.[13]

All three of these international consensus documents recognize the vulnerability of some human populations to exploitation and harm. Some vulnerable populations cannot advocate for or defend themselves against exploitation. Human embryos constitute one of those vulnerable populations. To date, the scientific and legal communities have not exercised responsible limitations to prevent exploitation and harm to human embryos in research. Instead, the scientific community has generally ignored the intrinsic ethical problem produced by research using embryonic human beings. Legally, human embryos are considered property.

The Gruesome Proposal to Create Human Beings Solely for the Purpose of Experimentation (Human Embryonic Models, a.k.a. HEMs).

Worldwide, most communities of researchers recoil at the creation of human beings solely for the utility and benefit of other human beings. Yet this is precisely the kind of research currently underway worldwide.[14,15] It is a particularly gruesome concept to create vulnerable human beings for the explicit purpose of experimentation. Even worse is the creation of human beings for the purpose of deforming them to study human deformities. It violates the principles of respect for persons as well as beneficence and justice outlined in the Hippocratic Oath, the Declaration of Helsinki, and the Belmont Report, all of which still serve as the basis for research ethics in the United States. A recent article in the lay press gives an example of an attempt to normalize the creation of embryonic human beings for experimentation in order to induce the general public to accept the concept:

> Scientists in Cambridge have created synthetic mouse embryos in a lab, without using eggs or sperm, which show evidence of a brain and beating heart...
>
> ...Eventually, their ambition is to develop similar embryos from human stem cells - but this is still a long way off, and ethically much more complicated.
>
> At present, UK law permits human embryos to be studied in the laboratory only up to the fourteenth day of development, but there are no rules around synthetic embryos.
>
> Prof Robin Lovell-Badge, from the Francis Crick Institute, said that should change.
>
> "Given the similarity with real embryos, it follows that consideration also needs to be given as to whether and how such integrated stem cell-based embryo models should be regulated," he said.
>
> He added that it was important not to think of the embryo-like models "as being the real thing - even if they are getting close."[16]

The obvious problem is that, in fact, these "embryo models" are "the real thing." An entity with human DNA that has organized development through organogenesis meets the criteria for being a human embryo, i.e., a human being, even if that human being does not continue through subsequent development to birth. As previously noted in Condic's work, the ability of an organism to act in a coordinated manner towards the health and well-being of the organism as a whole is what characterizes that entity as a living organism.[11]

There is currently a proposal in the UK to eliminate the rule that human embryo experimentation must be stopped at 14 days post-fertilization, the so-called "14-day rule". The Code of Practice for the Generation and Use of Human Stem Cell-based Embryo Models was recently submitted to the UK Parliament for ratification in early 2025.[5] The reasons given for the relaxation of that rule are nothing short of horrific: allowing the creation of embryonic human beings called "Human Embryo Models" (HEMs) for the purposes of exposing these human beings to toxic drugs in order to study the resulting deformation and to use these human beings as subjects of drug experimentation. To quote from the Parliamentary Office of Science and Technology (POST) Report:[17]

[Note: references here are renumbered from the original POST Report and are cited below for availability in the end notes of this Committee Opinion.]

> HEMs can be generated from either of these stem cell types (hESCs or hiPSCs) using various methods.[18] These methods include controlling the space in which the cells grow, altering the nutrients supplied, and/or by genetically manipulating the cells.[15, 19, 20]
>
> Stakeholders from academia, ethics and policy are discussing the opportunities and challenges that these scientific advances may raise. The current debate is focused on how existing legislation may need to adapt to the emerging technology, and the wider ethical and societal debates.[21-28]

Classification of HEMs

> Guidelines drawn up in 2021 by the International Society for Stem Cell Research (ISSCR) classify HEMs into integrated and non-integrated classes. It also suggests that each be subject to different levels of regulations (see section Amendment of ISSCR guidelines (2021)).[29]

Non-Integrated HEMs

> Non-integrated HEMs only partially mimic the developing embryo. They do not include certain cell types (extra-embryonic cells) that are crucial to the development of the embryo. Therefore it is thought they lack the potential to develop into a fetus.[30-32] Non-integrated HEMs may include:
>
> - 2D micropatterns, where stem cells are grown in a controlled space to trigger their self-organisation properties of early development,[19]
> - gastruloids, which have features of a developmental stage of the embryo called gastrulation when the body outline forms (see Figure 1), [33-35]
> - models of the fluid-filled sac, called the amniotic sac, within which the embryo develops inside the body.[36, 37]
> - or early features of the developing nervous system (called neural tubes).[36]

Integrated HEMs

Integrated HEMs mimic the development of the entire embryo and contain both embryonic and extra-embryonic cell types. They are thought to have the potential to develop into a fetus.[38] Integrated HEMs can include:

- blastoids, that represent a developmental stage of the embryo called the blastocyst which occurs 5-7 days after fertilisation (see Figure 1),[39-43]
- models that represent human embryos up to 14 days after fertilisation,[15, 20]

What is being described and requested in the UK via POST Report is no less than allowance for the creation of human beings for the explicit purpose of experimenting on those human beings. The POST report describes the creation of human beings in order to expose those human beings to teratogens and to mass produce those human beings for pharmaceutical experimentation. This is a gross violation of the international consensus statements protecting the rights of human subjects in research.

Outlined below are the research agendas proposed in the POST report:

Potential Applications of HEMs

...Scientists argue that HEMs provide a sustainable way to supplement the supply of embryos that researchers need.[44] HEMs are seen as a key advance for understanding embryo development, for research progress and in developing clinical treatments.[45]

Early Pregnancy Loss and IVF Outcomes

The use of HEMs to study early embryonic development is relevant to conception naturally or via IVF. Approximately 50% of fertilised human eggs fail to develop during IVF treatment.[40, 46-48] Even after successful conception, 1 in 5 pregnancies are reported to end in miscarriages (CDP-2021-0128), and pregnancy-related conditions, such as pre-eclampsia, cause over 50,000 maternal and 500,000 fetal deaths worldwide (PN 527).[49-51] HEMs can provide detailed scientific data on biological mechanisms of early embryo development and this information can be used to improve IVF treatment outcomes and reduce risks of early pregnancy loss.[52]

Disease Modelling

In 2019 in the UK, approximately 1 in 46 births were diagnosed with congenital abnormalities.[53] HEMs can be used to investigate the origins of congenital abnormalities. HEMs can reflect the complexity of conditions

within a living organism and be developed to a particular stage that is most relevant for the disease.[54]

Researchers are generating HEMs to investigate various conditions such as:

- malformations of the fetus' spine,[55]
- the impact of disrupting key signals involved in the early development of the nervous system,[56]
- neurodegenerative diseases such as Huntington's,[56]
- and early heart development which could help understand congenital heart disease (CHD),([57]) one of the leading causes of death in newborns[58]
- In cases of rare diseases (CDP-2017-0105) where there are limited samples for research, HEMs offer the opportunity to model diseases from the patients' iPSCs.[59]

Toxicity Studies of the Developing Human Embryo

While most studies of teratogens (chemicals that cause harm to the growing embryo or fetus) are conducted on model organisms, such as mice, they do not capture species-specific responses.[60] For example, researchers have used HEMs to test Thalidomide, a morning-sickness drug that resulted in severe birth defects in humans. They found a stronger effect on HEMs compared to mouse embryo models.[61, 62]

Large-Scale Drug Discovery

In contrast to human embryos, HEMs can be produced in larger numbers to test multiple compounds for medicinal effects at the same time.[52, 63-66]

Source of Cell Therapy

HEMs are a potential way to generate materials for cell therapy (PN 567, PN 221) where cells are given to a patient for treatment (e.g., CAR T-cell therapy in cancer (PN 598)) or regenerative purposes (PN 620).[67-72]

None of the results of this proposed research will benefit the human beings who are the subjects of these experiments. It is clear that human embryonic models meet the criteria for human beings, although they are derived from stem cells. There is no legal advocate for these human beings created for abuse and exploitation. There needs to be a worldwide outcry against this premeditated horrific abuse of vulnerable human beings.

Ethical Treatment of Human Embryos in Assisted Reproductive Technology (ART) Practice:

The ethical treatment of human embryos in the IVF industry also calls for

limitations on what can and cannot be done with created embryos. AAPLOG recognizes that there are pro-life medical professionals of good conscience who reject IVF entirely because of its in vitro manipulation of young human life. Some also are concerned about laboratory experimentation with nascent human beings.

Other pro-life medical professionals of good conscience could potentially accept a form of IVF that is life-sparing but who are nonetheless opposed to the often life-destroying practices of the current IVF industry. As a profession that has pledged to protect all of our patients, including the most vulnerable, we must take a serious look at the facts about IVF.

IVF does not treat the underlying pathology that leads to infertility; it provides a technical workaround in hopes of producing a baby. Current IVF practice is often not life-affirming and never life-sparing. Current estimates for the number of embryos that do not survive or are destroyed, discarded, or frozen for storage under usual IVF practices range from 90-98%. Ghazal et al. wrote that the rate of embryo loss in the U.S. is 76.5% but pointedly did not take into account embryos discarded or cryopreserved; these additional embryo losses would give a rate of at least 90%.[73] Likewise, Kovalevsky and Patrizio calculate wastage of embryos as 85% but do not include the number of embryos discarded or lost during thawing from cryopreservation, stating that their 85% rate of loss "greatly underestimates the overall loss."[74] Adjustments for these additional losses would raise the rate of loss over 90%. Gleicher et al. note regarding genetic testing that "Because of the high false-positivity rate, a large number of perfectly normal embryos are now routinely discarded which, if transferred, in surprisingly high percentages still would result in normal births." [75]

Moreover, IVF can pose distinct risks both to mothers and to babies. Before any attempts at IVF, there should be counseling to provide complete informed consent regarding the facts of IVF, including efficiencies, risks, and ethical considerations. Also, before attempting IVF, every effort should be made to diagnose, treat, and resolve the underlying causes of infertility.[76, 77] Restorative reproductive medicine has been documented to improve fertility rates even after IVF failure.[78, 79] Accurate diagnosis and targeted treatment of the underlying causes of infertility address the real needs of patients and can improve long-term health well beyond pregnancy.

However, if IVF is to be used, it should conform to the respect of human persons inherent in the Hippocratic Oath and also reflected in the 2016 international consensus document, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) on the treatment of human subjects which states that "the rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society"[80]

It should be recognized that IVF results in increased risk to both the moth-

er and the fetus. According to the Society for Maternal-Fetal Medicine, IVF is associated with increased risk for several adverse maternal and perinatal outcomes, including monozygotic twins (even with single embryo transfer), multifetal pregnancy, placental implantation disorders, hypertensive disorders of pregnancy, and stillbirth, Singleton pregnancies conceived by IVF also have a higher risk of preterm birth and small for gestational age infants. Additionally, pregnancies conceived with Intracytoplasmic Sperm Injection (ICSI) have a higher rate of de novo chromosomal abnormalities. [81]

Brief Review of the Process of IVF

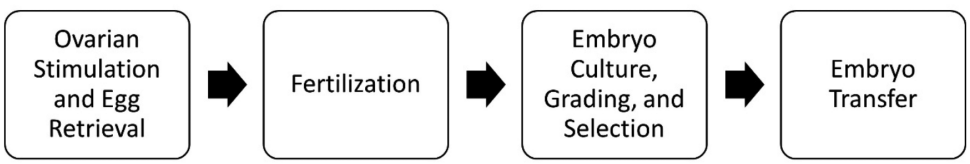

Figure 2 – IVF Process

Ovarian Stimulation and Egg Retrieval

The process of IVF begins with the collection of eggs and sperm. The collection of eggs most often involves hormonal stimulation to synchronize egg maturation. High-dose hormonal stimulation of the ovaries is done to produce multiple eggs at one time rather than the single egg usually matured per cycle. The eggs are harvested trans-vaginally under ultrasound guidance and then either frozen or fertilized.

Fertilization

At this stage, the procedure varies depending on where and how fertilization occurs.

In traditional IVF, which accounts for 99% of procedures, fertilization occurs in vitro. The developmental stages that normally would have occurred in the fallopian tube during transfer to the uterus occur instead in culture media in the petri dish for 3-5 days. Embryos that survive for 3-5 days are candidates for transfer to a uterus.

In Gamete Intra-Fallopian Transfer (GIFT), the eggs and sperm are both transferred to the fallopian tube, which is the normal site of fertilization Thus, GIFT attempts to utilize the natural environment for fertilization and the first days of human development.

Zygote Intra-Fallopian Transfer (ZIFT) combines egg and sperm in a pe-

tri dish for fertilization, as is done with traditional IVF. However, the zygote formed is transferred on day 1 to the fallopian tube, approximating the site and environment where the zygote would have been produced in vivo. This method also attempts to utilize the natural environment for early embryo development.

Intra-cytoplasmic sperm Injection (ICSI) is a variation of IVF used for sperm-related fertilization failures. The lab technician injects one sperm into each egg under a microscope. After further growth in the lab dish, the embryo is transferred to the uterus as in traditional IVF. There is some increased concern with this procedure since more parts of the sperm enter the egg than in natural in vivo fertilization, and also the significant manipulation of the egg involved.[82-85]

Embryo Culture, Grading, and Selection

For GIFT and ZIFT, there is no culturing or grading, as the early days of embryo development take place in the normal in-vivo environment.

In traditional IVF, however, embryos are evaluated and graded. Some embryos do not survive and grow but instead perish in the dish. Embryos that survive 2-5 days' culture are evaluated by various methods and are "graded" by subjective microscope inspection to indicate a judgment of their potential for implantation and development.[86, 87] Recently, there has been a movement to incorporate Artificial Intelligence (AI) into the grading of embryo quality.[88] Theoretically, those judged as "high-quality" embryos have a better chance of implantation and gestation to birth, which is the endpoint for grading. However, studies show that even so-called "low-quality" embryos can develop into normal babies.[89] Grading criteria are based solely on the predicted likelihood of subsequent implantation and gestation to birth, not on whether or not the embryo is, in fact, a living human being.

Genetic testing is also used to evaluate embryo quality and specifically to select for or against embryos with various genetic traits. Preimplantation genetic testing (PGT, sometimes termed PGD for preimplantation genetic diagnosis or PGS for preimplantation genetic screening) involves making a hole in the zona pellucida, extracting about five cells from the Blastocyst, and then freezing the embryo while the genetic analysis is conducted.[90] The cell(s) undergoes genetic analysis for "fitness." Screening may be for aneuploidies (different chromosome numbers, e.g., trisomies such as Down syndrome) or for specific genetic compositions and traits, including for sex selection and even potential adult-onset disorders (e.g., breast cancer or Huntington's disease). While some early studies showed increased success at live birth using genetic selection of the desired embryos, other recent studies have found the opposite. One study found

> a significantly lower rate of pregnancies in the women who underwent genetic screening, however. Only 25% achieved ongoing pregnancies, compared with 37% of women who were not screened (rate ratio 0.69, 95%

confidence interval 0.51 to 0.93).

> The women randomised to preimplantation genetic screening also had a significantly lower rate of live births, at 24%, compared with 35% in women who were not screened (0.68, 0.50 to 0.92). [91]

Several studies indicate that PGT lowers the live birth rate,[91] does not improve pregnancy, implantation, or live birth rates,[92] and should not be used except perhaps for research studies.[93] Despite these findings, PGT has become routine as part of IVF. As with visual grading, some embryos labeled "low quality" or "abnormal" by PGT produce healthy babies.[94, 95] As one might expect, not all embryos survive having some of their cells removed.

Clinics may offer PGT or other "add-ons" as incentives, claiming they improve the efficiency and survival of embryos to live births. IVF clinics are rated by patients as well as insurance companies based partly on their pregnancy and live birth rates, leading to significant pressure on the clinic to do anything they can to improve the rate of these outcomes. This is a conflict of interest in ethical decision-making. A Cochrane special report noted that "none of the IVF add-ons are supported by high-quality evidence that the add-on is effective and safe."[96]

Embryo Transfer

If embryos survive culture, they can be transferred to the endometrial cavity. The number of embryos and their age in days when transferred are important considerations for subsequent gestation. In the past, anywhere from two to six embryos were transferred to give a better chance for at least one to implant in the uterine lining and continue development and gestation. However, this led to increased multiple pregnancies (including high-order multiple gestations), which is a health risk to both the mother and the babies. In this circumstance, some practitioners recommend "multifetal pregnancy reduction" to end the lives of some of the fetuses and "reduce" the pregnancy down to no more than two. While this might reduce maternal risks to some extent, multifetal pregnancy reduction can endanger all of the developing fetuses, does not completely eliminate risks associated with multiple pregnancies, and can have adverse psychological consequences for the mother.[97, 98] Additionally, multifetal pregnancy reduction is clearly the intentional ending of human lives.

Current guidelines in the United States,[99] as well as in other countries,[100] limit the number of embryos transferred each cycle. In the U.S., the recommendation is for only one embryo (single embryo transfer, SET) to be transferred in healthy young women, with two or at most three embryos as a limit in older women, while women at the extremes of reproductive life may be offered up to a limit of four.

Embryo Disposition: numbers created, destroyed, frozen, transferred, born

The latest global estimate is that at least 12 million babies were born via

IVF between 1978 and 2022.[101] Less well-known are estimates of the number of embryos created that led to the 12 million births.

It has been estimated that the average blastocyst conversion rate (percent of zygotes formed in vitro that develop into blastocysts 5-6 days post-fertilization) is 66.7%.[10] This means that 33.3% of the zygotes (one-celled embryos) do not proceed to the blastocyst stage in vitro.

Although we do not know for certain the rate of blastocyst conversion under natural conditions (in vivo), Jarvis calculates that, under natural conditions, embryo loss is approximately 10-40% before implantation.[46] It also must be noted that there are cases in which the embryo starts to implant, but the woman never even knows she is pregnant.

The embryos that progress at least 2-3 days are graded for quality and either transferred to the mother, frozen, or discarded. Of those that are transferred to the mother, the majority do not survive. Embryo wastage is a term used to refer to the percentage of transferred embryos that do not result in the birth of the infant. [73] Embryo wastage rates have decreased from a high of 90% in 1995 to 76.5% in 2013.[73,74] Despite this improvement, nearly three in four transferred embryos do not survive to live birth. This is heavily dependent on the mother's age.

Embryos that are not transferred by fresh cycle are either discarded or frozen. "Fresh cycle" refers to transferring embryos created during the egg retrieval cycle and not freezing those embryos. "Frozen cycle" refers to the transfer of embryos previously frozen. One reference notes that an IVF clinic's optimal financial business plan is to harvest 15 eggs in a single "fresh" cycle and fertilize all eggs, knowing that embryos will be created in the process but not transferred in that fresh cycle.[102]

"Supernumerary embryos are expected."[102] The terms "supernumerary," "extra," or "leftover" are often applied to the human embryos created but not selected for fresh cycle transfer to the uterus. The high-quality embryos are sometimes frozen, perhaps for use in future transfers. Still, if their screening delegates them to a grade of low quality or genetically undesirable, the embryos are discarded. In many cases, a family will not transfer their remaining frozen embryos, regardless of their graded quality, once a desired number of children is reached. Embryos that don't meet desired characteristics are discarded, including in cases of embryo sex selection, which can lead to the disposal of healthy embryos.[103]

Cryopreservation is sometimes considered a life-sparing practice to preserve live embryos for future transfer. As with the number of embryos discarded, most clinics do not report the number of embryos they freeze. In 2003, the first survey of clinics found 400,000 embryos in freezers in the U.S.[104] A 2020 study indicated over 1.2 million embryos were then in storage freezers.[105] Some estimate that there are now 1.5 million embryos in freezers in the U.S. alone.[106]

Theoretically, those judged as "high-quality" embryos have a better chance of implantation and gestation to birth, which is the endpoint for grad-

ing. However, studies show that even so-called "low-quality" embryos can develop into normal babies. Mosaic embryos are embryos that contain both euploid and aneuploid cells on prenatal genetic testing. Although they have a lower implantation rate, mosaic embryos are capable of producing normal infants.[107]The current practice is for most clinics to transfer mosaic embryos

It is difficult to estimate the number of embryos created to result in the 12 million live births from IVF. Data from the Human Fertilization &Embryology Authority (HFEA) in the UK indicate that in that country, 1.7 million embryos created for IVF have been thrown away, and only 7% lead to pregnancy.[108, 109] The HFEA has longitudinal data about the pregnancy rate per embryo transferred, which improved over the time of their data collection but has never exceeded 1 out of 3 embryos transferred (approximately 35%).

If we assume the best scenario of a 35% birth rate per embryo transferred worldwide, then achieving the 12 million estimated births from IVF necessitated the creation and transfer of, at the very least, 34 million embryos. This means that at least 22 million embryos who reached the capacity to transfer did not survive. And this 22 million does not include the embryos who died, were discarded, or were frozen and not transferred.

As can be seen in Figure 3, there are multiple times in the process in which embryos do not survive, are discarded, or are frozen, possibly in perpetuity. As pro-life professionals who view all products of sperm-egg fusion as human embryos deserving of dignity and respect, the number of embryos that are created only to be discarded, die, or be frozen in perpetuity is concerning.

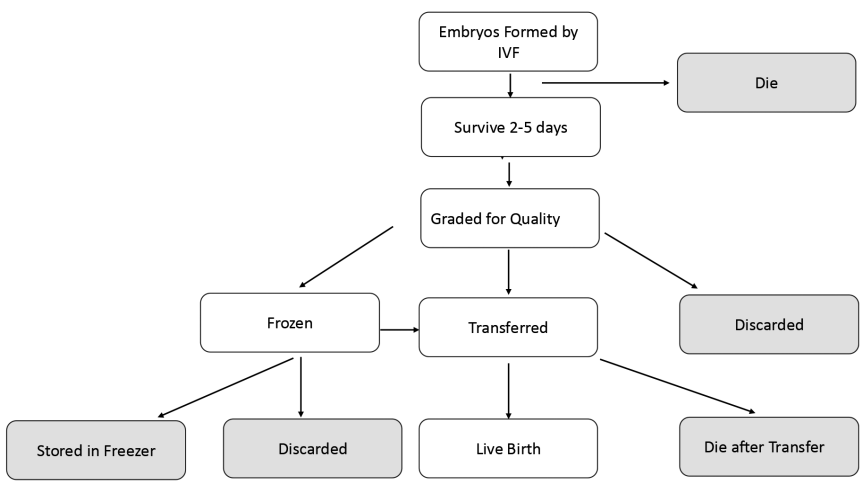

Figure 3 – Outcome of Embryos Created by IVF

The survival of embryos after freezing is a significant concern. Cryo-

preservation involves protecting the embryo by infusing cryo-preservative solutions into its cells, followed by either a slow freezing process or flash freezing (vitrification).[110] The process works because there are few cells in the young embryo, allowing the cryo-preservative to penetrate most cells and prevent damaging ice crystal formation. Theoretically, freezing at liquid nitrogen temperatures (-320° F/-196 ° C) can preserve embryos without cell degradation over long periods. However, some recent studies indicate that older embryos may suffer some damage from freezing, as well as from genetic testing.[111] However, the greatest danger is from ice crystals that form upon thawing, which destroys many embryos. Previously, a 50% survival rate after freezing and thawing was considered standard. More recently, for some clinics that use good techniques and care, survival rates in some cases can be up to 96%.[112] The disparity in survival rates after freezing means that freezing and thawing itself is technique-dependent, and poor technique can lead to the deaths of many embryos.

Some parents of frozen embryos offer their embryos for adoption or donation to other infertile couples. As a result, instead of lying dormant in a freezer, some of these embryos have been born.[113] In other cases, couples may designate that their frozen embryos be thawed and discarded. Frozen embryos that are abandoned and unclaimed may also be discarded.[114] In other cases, embryos are donated for research, where they are destroyed through experimentation.

Rarely, IVF has also been used to create embryos as "savior siblings." Embryos are created by parents of a born child who has a lethal diagnosis, with the idea that a healthy, genetically-matched embryo can be gestated and this sibling, once born, can be an adult stem cell donor or even a tissue donor.[115] All of the other embryos either remain in frozen storage or are discarded.

There are life-sparing techniques that could be employed for IVF procedures. These include:

a) prohibiting the destruction of human embryos,
b) limiting the number of embryos created per cycle based on age and embryo survival rates in culture.
c) limiting the number of embryos transferred each cycle, consistent with current ASRM guidelines,[99]
d) including the use of single-embryo transfer (SET), and
e) limiting embryo freezing

Natural-cycle and minimal-stimulation IVF, which utilize no or minimal added hormonal boost, show consistently good data for Live Birth Rate and overall IVF success. Several studies have contradicted the assumption that more oocytes lead to better success; the advantages of decreased risk to women from ovarian hyperstimulation are significant. These milder IVF protocols are also less costly than traditional IVF.[8,116-120]

Another proposal is to couple life-sparing practices of IVF with egg-freez-

ing rather than embryo-freezing. Freezing eggs does not obviate all ethical concerns but poses fewer potential problems than embryo freezing.[121]

Final Considerations

In summary, the recognition of human beings in the embryo stage calls for an ethical re-evaluation of both research practices to conform with international consensus statements on human subject research and some practices in the ART/IVF industry. Our common humanity requires justice and beneficence for all human beings, regardless of age or circumstances of our beginnings.

Human beings conceived in vitro by scientific bioengineering are no less human than those conceived in vivo by natural processes. Therefore, they have the same moral significance and require the same bioethical considerations. IVF embryos are human beings and should be regarded as such, not as commercial products. The current legal status of embryo dispute cases, where embryos have been conceived in IVF, is determined under property law, treating the embryos as commercial property. Recognition of the humanity of the human embryo will require embryo dispute cases to be determined under family law, recognizing that there is a disposition in the best interests of the embryo. Parents must retain legal oversight and responsibility for their children, even when those children are still tiny, vulnerable embryos. Parents themselves deserve legal protection as the guardians of their children. Parents deserve full informed consent. Parents should retain legal recourse for the negligent loss of their children as embryos.

Summary of Recommendations

This committee opinion is intended to promote the dignity and life of the human embryo and promote the reduction of harms and risks to the embryo. AAPLOG does not endorse a formal position on the practice of IVF and acknowledges that there is a diversity of opinion among its members due to the ethical challenges in ART. AAPLOG does take the position that embryo destruction during the process of IVF is unethical.

For Assisted Reproductive Technology, we recommend the following:

- Before attempting IVF, all women should receive complete informed consent, and every effort should be made to utilize restorative reproductive medicine as a treatment for infertility.
- All human embryos deserve dignity and respect. Given the loss of embryos from freeze-thaw and the sheer number frozen in perpetuity, AAPLOG discourages freezing of embryos.
- Only procedures that offer the prospect of direct benefit to the embryos or pose a minimal risk should be allowed.
- Freezing of eggs does not carry the same moral implications as freezing of embryos and should be encouraged over freezing of embryos.

- The number of eggs inseminated should be limited depending on the patient's age and intended family planning.
- The number of embryos transferred each cycle should be limited according to current ASRM guidelines.
- PGT in all forms (PGT-A, PGT-M, PGT-Translocation) should be discontinued.
- Selective reduction of embryos or fetuses for multifetal pregnancies should be discontinued. Selective reduction is the intentional destruction of human life. Instead, the number of embryos transferred should be limited to diminish the ethical dilemmas of multifetal pregnancies.
- Encourage minimal stimulation or natural cycle protocols for IVF.
- Embryo adoption should be encouraged as an ethical and compassionate alternative to discarding them or experimenting on them.
- Deliberate destruction of embryos by any means is unethical.
- Since human embryos are human beings and not objects, embryo dispute cases should be settled under family law, not property law.
- Regulatory oversight of the IVF industry is sorely needed. Transparency provides accountability. Transparency and mandatory reporting of all data regarding IVF and ART practices, including the number of embryos created, transferred, destroyed, discarded, cryopreserved, and patient outcomes, should be legally required.
- Long-term data on health outcomes of ART should be a research priority (including mothers, babies, egg donors, and surrogates).

For Research, we recommend the following:

- An immediate worldwide moratorium on the creation of both nonintegrated and integrated Human Embryonic Models (HEMs) should be instituted.
- The creation of human embryos for research should be prohibited.
- Creation of embryos other than by means of the fusion of a human sperm and a human egg should be prohibited.
- Manipulation, where a human embryo is intentionally created or modified to include a heritable genetic modification or intentionally exposed to teratogenic materials, should be prohibited.
- Any proposed research on embryos should conform to the international consensus guidelines on human subject research, including requirements that the study design ensures that human embryos are not the subject of destructive, harmful, or deforming research.

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