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FEATURE ARTICLE

Healthy Justice: A Liberation Approach to Justice in Health Care

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Introduction

Without social justice, we cannot promote population health nor a universal public health system necessary to support it. In the words of Norman Daniels "social justice is good for our health."[1] Catholic social teaching has important insights to contribute to the social justice debate in health and public health care. Drawing upon this tradition, I will explore the concepts of justice and the common good and their implications for justice in health care.

Lisa Cahill proposes that theological bioethics should make justice in access to health care resources its first priority.[2] This is my point of departure. Along with the notion of the preferential option for the poor, one of the basic principles of the Catholic social tradition, this is an option that comes from Christological faith.[3]

This option challenges us to look at reality, analyze it, and act in the world from a perspective that rises from below. This challenge begins with two invitations: first, it invites us to join with the poor and marginalized to share their lives and see reality from their perspective. Second, it invites us to understand suffering and poverty from the perspective of those who are poor and carry great burdens. If we accept these two invitations, we will discover what the suffering of the poor concretely means and how can it open our eyes to a new understanding of unfair social relations which create exclusion and exploitation of the weakest ones. Only among the poor, can we live the preferential option for the poor.[4] This option leads us to realize that the poor are human beings and not a sociological concept, nor an abstract Christian principle. In addition, it stresses that the poor have their power in history; they are not simply masses that can be manipulated or a context to apply our theories. If we want a real

transformation of reality, we need to act with the poor, from below.

The preferential option for the poor impacts the way in which to do theological bioethics. It forces theologians to turn from a bioethics from above to a bioethics from below. Therefore, this way of doing bioethics will be from the perspective of the poor in which issues such as justice, health, and universal health care will be a priority. From the perspective of the poor, it is possible to empower the poor and propose actions to promote justice in health in a participatory way.

My approach to justice in health and public health care is a dialogical process that begins with those who are excluded in order to empower them to participate in the decision-making process in the social and political arena. Thus, dialogue is an intrinsic aspect in the sense of a broad participation that includes the poor and all those who do not have a voice in the social arena. Hence, I divide my discussion into three topics. First, I present the issue of justice in public health. Second, I define social justice and the common good as they are expressed by the Catholic social tradition. Third, I show how the moral imperative of justice in health care (preventive and curative) and in the Catholic social tradition offers some insights to promote population health.

1. Health: Justice in Public Health[5]

Justice in health promotion and health care does not exist on its own. It needs a fair society. In other words, social justice is absolutely essential to population health. Many situations that put population health at risk are linked to the social conditions of life.[6] Poverty is the number one cause of individual and social vulnerability and early death. Therefore, actions to promote social justice that address poverty and struggle against social inequalities are indispensable to promote justice in health. Unfortunately, the health sector itself does not have enough power to promote justice in health care in order to support population health. Inequalities in health care are a consequence of an unequal society that creates unfair structures to benefit a small and privileged group in the world. At the same time, these inequalities cause massive suffering among the greater part of the world's population. Those who are forced to live a miserable life and are without opportunities are vulnerable to all kinds of diseases and social insecurity.

These vulnerable people are the poor who do not have a face. The privileged ones do not see them, except as an undefined mass of misery. In theological language, these are crucified people who are abandoned to their crosses without hope of social redemption. It is not possible to promote social justice if we do not know who these suffering people are. We cannot promote justice in health promotion and health care if we do not know the suffering of this crucified people; if we do not know that they have

faces, families, and dreams; if we do not know their names. They are José, Maria, Dominique, Julia, Tú, Jun, Bambam, Shinbin, Michael, Bryan, Samantha. They are human beings as you and I. Humans who think and feel, smile and cry, enjoy and suffer; who need to drink clean water and eat healthy food; who need clothes and a home; who need to grow and die after a life lived according to their beliefs, principles, and culture. They are human beings who want to develop their full humanity and expand their world through education and work as all children of Adam. They are people who are fragile and affected by death, who get sick and need health assistance. Again, these crucified people are worthy people like you and I.

The first step to promote social justice is to recognize that the poor have faces and lives. Simone Weil, the French philosopher, affirmed that the poor are invisible to those in society who are not poor and who have power in their hands. According to her, the world never will be better until we recognize the poor as individuals who share the common human condition of fragility. This recognition can only happen in two ways. The first is through our own experience of suffering that happens through a deep spiritual experience of meeting Jesus in his cross or our own social poverty. Both of these reveal the contingency and the fragility of our human lives. The second is through our courage to live with the poor and share their lives.[7]

Norman Daniels affirms that a theory of justice is the first step to promote justice in health care and population health because a theory of justice "can guide our practice with regard to health."[8] But if we begin with a theory of justice, we might make abstract statements that are so beautiful and logical from a philosophical perspective, but remain far from reality and be impossible to apply realistically. Daniels' approach also proposes to address a virtual reality that is disconnected from the real needs of those we aim to help. In addition, beginning with a theory of justice from above to solve problems from below does not require democratic participation, does not recognize the faces of those who should benefit from it, and might be authoritarian when applied as well.[9]

I appreciate Daniels' theory of justice, but it is insufficient. He forgets the poor people who are suffering in an unjust reality that he wants to fix with a theory. Daniels does not analyze the mechanisms of oppression that prevent the poor from living a worthy life and having opportunities to flourish. Consequently, he thinks that the liberal model of development is sufficient to promote justice in health, and a reform is sufficient to join market freedom with economic growth and equality with social development.

A theory of justice could be a second or third step. The first step should be to recognize the face of the poor, to understand their suffering and share their lives. Thus, the analysis of the social reality must arise from the *locus* of the

poor. Social transformation requires empowering the poor to participate in the decision-making process. In this way, we will know their health needs. Then, we can move to a theory of social justice in dialogue with the whole society. A theory may be useful, not because it has the solution for all social problems, but as another interlocutor in a dialogic construction. Hence, a dialectical approach from below respects the particular specificities of the local context, the particularities of cultures, and international relations. As dialectic, it begins giving voice to those who do not have one.

> Nevertheless, among poor people we need instruments to analyze reality. We need to interact with the poor with a greater understanding of the mechanisms of oppression, exclusion, social injustice, and health inequalities. Social sciences provide these instruments. It is our responsibility to use them for analyzing the reality and translating the results into a language that the poor can understand. This must be a dialogic process with the poor within their reality and not in a seat of a university where the poor do not yet have a place.

Social analysis cannot be something given by scientists, intellectuals, or theologians to the poor because they do not have anything to offer, but only need to learn. It is necessary to recognize that the poor are not only passive receptors of a dominant mentality without any knowledge. The poor have their very specific kind of knowledge that keeps them standing amid situations of oppression and marginalization. This knowledge is not systematic as is scientific knowledge. It is fragmented and scattered, but it reveals a popular wisdom. It shows the power of the poor in history. Hence, dialogue and dialectical dynamics are indispensable requirements for bioethical praxis as well as virtues such as humility and prudence.

Paul Farmer exemplifies this approach. In his book *Pathologies of Power*, in dialogue with liberation theology, he talks *with* the poor in their *locus* of suffering in a concrete place, Haiti. There, as a physician, he worked with the poor. This experience gave him a perspective to understand the suffering of the poor and its causes. Sharing his medical gifts with the poor around the world, he noted that there are structures that cause suffering among the poor and prevent them from accessing a life with dignity. Farmer encourages a *pragmatic solidarity.*[10] He invites people to leave their comfort zone and to join the poor working with them toward a better world. He also affirms that "the silence of the poor" must be broken and that this requires compassion and solidarity.[11]

Breaking the silence of the poor is necessary to meet those who are poor, listen to them, and give them voices. We will never break this silence if we are far from the poor. Without interaction with the poor, we see them only as a passive mass that merely receives a theory of justice that aims and promotes reforms while supporting the neoliberal economic model. Any neoliberal model is from

above and marginalizes human lives that cannot compete in the marketplace. Giving voice to the poor requires knowing who the poor are and, at the same time, our compassion and solidarity move us to be with the poor. Among the poor, we realize that our intellectual instruments must be recreated to address their reality. The poor have something to offer to recreate a new world. We need to dialogue with them. I argue for pragmatic solidarity, humility, and creativity together with the poor.

> Structural violence is a key concept to understand the suffering of the poor. Farmer affirms: "Today, the world's poor are the chief victims of structural violence – a violence that has thus far defied the analysis of many who seek to understand the nature and distribution of extreme suffering. (…) The task at hand, if this silence is to be broken, is to identify the forces that conspire together to promote suffering, with the understanding that these are differentially weighted in different settings."[12]

Social analysis far from the poor tends not to see the poor themselves and believes that reforms are enough to promote social justice and justice in health care. In addition, this approach supports the *status quo* of those who are in a privileged situation. Theories of justice that are not situated in the *locus* of the poor are neither dialogic, nor democratic because they dispense the contribution of the poor. Consequently, they are elitist and support welfarist policies as a way to combat poverty and promote justice. Welfarism only ensures that the poor are able to survive and do not die of hunger quickly. It is necessary as an immediate action, but it must be overcome as soon as possible in order to empower the poor. Welfarism makes the poor dependent upon the neoliberal system in a cruel relationship between welfare and exploitation.[13]

Promoting justice in health promotion and health care requires struggling against the inequalities in health care that are the consequences of social injustice. Therefore, justice in health care requires social justice. In addition, justice in health care is not only to distribute health care; rather it requires promoting population health necessary to create possibilities for people to improve their lives. There are two ways of considering population health. First, it addresses social justice, it empowers people to live in good social conditions, it helps them to develop their lives with dignity. Justice in health care must be viewed as a societal issue and not isolated from it.[14] In order to achieve justice, it is necessary to value justice in some "spaces" such as health care.[15] Second, justice must be viewed in the specific context of health, as a precondition that enables people to develop their lives. Hence, it is crucial to address challenges of distribution of health and health care, the social determinants of health, and the allocation of resources in health care. This will foster the social arrangements that will strengthen social opportunities and break structural violence. These challenges should be met in a dialogic way with the poor to break through their

silence and to empower their working collaboratively, creatively, and prophetically.

2. Theology: Justice and the Common Good in the Catholic Tradition

The Catholic social tradition offers us a contribution to promote social justice and justice in health promotion and health care. First of all, this teaching should be used dialogically among the poor. Catholic social teaching must allow itself to be confronted by the poor and their experience of structural violence and also to be recreated in light of this interaction. Otherwise, Catholic social teaching runs the risk of becoming just another abstract theory of justice. On the other side, Catholic social teaching, through prophetic voices, should dialogue with the secular world to advocate for the poor. Theologians must act as a bridge between the poor and the secular arena in order to give voice to the poor.

Shortly, I will explain a few elements that shape Catholic social teaching about justice and the common good. However, I will not accomplish this through conceptual explanations alone. Rather, I will do it from the standpoint of my experience working with the poor in grassroots communities in Brazil, particularly with volunteers of Pastoral of Health to promote a universal health care system. Justice and the common good in Catholic social tradition are social principles that arise from an experience of faith and a theological space. This space is the reality of the poor. Jon Sobrino affirms that the reality of the poor is the theological space of Christology in which we contemplate the face of the crucified Jesus in the face of crucified people.[16] These faces of suffering invite us to proclaim: "Blessed are the poor because they belong to the Kingdom of God" (Lk 6:20). This blessing is Jesus' appeal to struggle for justice in our historical time with those who are crying out for justice. Therefore, justice is grounded in our faith in Jesus that leads us to struggle for social justice from the perspective of the poor. Joining with the poor is a precondition for justice and articulating a theological bioethics from below.

The common good is grounded in the fact that all human beings belong to the same human community and have the right to enjoy all the goods that nature can offer in order to develop their lives.[17] The good of all human persons is connected to each person's ability to participate in the common good in the world that is God's gift. The Second Vatican Council affirms that the common good is "the sum of those conditions of social life which allow social groups and individual members relatively thorough and ready access to their own fulfillment."[18] Thus, the fair distribution of the common good is the duty of all members of the civil society.

The integral development of the human being depends upon each person having the opportunity to participate in the common good and, at the same time, to collaborate in the development of goods and their just distribution. Participation in the common good requires both

contribution and distribution in order to make goods available for all to promote social justice.[19] There is a circular relationship between contribution and distribution of the common good for social justice that requires a conception of humanity as a community of solidarity. "From a common good perspective, therefore, justice calls for the minimal level of solidarity required to enable all societies to live with basic dignity."[20]

Pope John Paul II presents the principle of solidarity as a moral and social virtue necessary to social justice. He affirms that solidarity "is not a feeling of vague compassion or shallow distress at the misfortunes of so many people, both near and far. On the contrary, it is a firm and persevering determination to commit oneself to the common good; that is to say, to the good of all and of each individual, because we are all really responsible for all."[21] Catholic social teaching has a communal vision of humanity and the relationship between people at local and global levels in its purview. As a community, all participate in the same human condition in which all are invited to collaborate with each other. The goal is an integral development of each person and of the whole community. Solidarity strengthens people in their active social involvement and recognizes the needs of each one leading to a mutual construction of a society that allows for integral human development.

Solidarity is necessary in order to share goods in which all can participate in the common good and build a good life in a just society. Catholic social teaching affirms that social justice requires *commutative justice* and *distributive justice* in order to empower all people to be able to participate in the common good.[22] Commutative justice is the contribution that all people are invited to give towards developing and strengthening the common good. All people have a duty to contribute towards building the social life in which all are able to participate in social goods. Social institutions are responsible for organizing social goods and making them available to all. Each person contributes to the common good according to his/her conditions and from his/her social space. Distributive justice answers to commutative justice by making the goods created available to all members of the civil society so they can meet their needs to construct a life with full dignity. Solidarity requires us to address social justice in terms of commutative and distributive justice. Without solidarity, it is not possible to empower those who are currently prevented from participating in the common good and who suffer "exclusion from social life and from participation in the common good of the human community."[23]

Solidarity leads us to join the poor in their own *locus*. Social justice should empower them to participate and contribute to the decision-making process of public political life that will make the common good accessible for all.

The preferential option for the poor gives us a perspective that touches the reality

of the poor in a way that empowers them to be agents of justice. Justice means that all members of civil society participate in the common good in a circular relationship between contribution and distribution (justice as a means) toward social justice (justice as an end). Everybody is called to give his/her contribution to growing the common good at the individual, political, and institutional levels of society.

The common good is a public good because it addresses the basic needs of human beings. In light of the preferential option for the poor, distributive justice makes the goods accessible to all through actions that begin from below, from those who suffer due to a lack of goods to meet their basic needs.

Justice and the common good are directly connected with the preferential option for the poor and solidarity. Among the poor, it is possible to see the harms that social injustice causes to human lives. With the poor, the first experience of solidarity is to share what they do not have. The situation of suffering and oppression draws the poor into a community united by their common experience of vulnerability and misery. They share their lives, sufferings, problems, and whatever crumbs they have available in order to keep the weakest ones alive. This is the first thing we learn with the poor. The poor live their lives full of insecurity due to the way in which social injustice prevents them from participating in the common good.

Catholic social teaching aims to promote the integral development of human beings in a communal perspective. It does not provide a framework to be applied, but offers some principles for dialogue. Justice and the common good are human values that point to any social contexts where all share the same human condition and dignity. They are completed by the preferential option for the poor that reveals the faces of those who are prevented from participating in the common good. The poor cry out for justice, freedom, and for conditions which enable them to participate in the common good. The preferential option for the poor brings the principle of social justice and the common good into dialogue with the poor and their reality to foster social transformation.

3. Health and Theology: An Approach between Catholic Tradition and Public Health

Lisa Sowle Cahill affirms that theological bioethics should reach beyond national health care reforms "to urge responsibility for global health inequities."[24] I stated before that reforms are not enough to foster social transformation. It is necessary to promote social justice and justice in health. Reformist mentalities hold the *status quo* of elites and support the neoliberal model of development that history has proven is not fair. This model has created more inequalities by perpetuating and generating structures of violence that act against the poor and do not provide opportunities for them to participate in political and social arenas as agents. The reformist model keeps the

poor as a *mass* to be manipulated in ways that serve the interests of those with economic power. A theological bioethics that focuses on inequalities in health at local and global levels should be prophetic and struggle for social transformation together with those who are the last ones of societies. For that, it is essential to go to the *locus* of the poor and work together in creative ways.

Among the poor, as the Brazilian pedagogue Paulo Freire states, the world must be re-read in context to recreate the world.[25] The poor have a knowledge that can help them to recreate the world. A dialogical interaction must happen between those who have systematic knowledge, as scientists and theologians, and those who have a popular, fragmented, and experiential knowledge, that is, the poor. The synthesis of this dialogue allows creative ways to recreate the world and presents alternatives for a new society.

The knowledge of the poor is from resistance to structural violence. It is also a creative knowing that allows the poor to adapt to situations of marginalization and insecurity. The poor might know that they are victims of social injustice, but their popular knowledge is limited in its ability to explain the mechanisms of oppression. Theological knowledge by itself is also insufficient to explain these mechanisms, even when it explains these mechanisms from categories such as 'social sin' and 'structural sin'. Social sciences provide tools to understand them. The dialogue between theology and social sciences must include the poor.

An approach between Catholic social teaching as it relates to public health first leads us to join the poor by sharing their lives. According to the principles of justice and the common good, health is a good to be shared by all. Moreover, social justice requires solidarity in a way that addresses commutative and distributive justice.

Paul Farmer affirms the role of health professionals in promoting justice in health and proposes that the preferential option for the poor challenges these professionals to work with the poor.[26] As one health worker, Farmer affirms that health care cannot be subjected to the laws of the market and become a commodity. Prophetic voices in health care are necessary to act against structural violence.[27] Dialogue with the poor works towards meeting their lives as they experience them and guides us to struggle with them for social justice and justice in health care. These are requirements to foster prophetic voices.

On the one hand, social justice is necessary to address the social determinants of health to promote population health. On the other hand, a solid universal public health system – that works together with other social areas and supports population health – is also essential. This public health system must focus on primary care with actions that include education in health, prevention, and early diagnosis and treatment.

Primary care should work in interaction with the local population such as health professionals working as a team which has contact with the community and knows the local epidemiological reality. Small nuclei of health care centers or clinics among communities are a way to allow access to health professionals as well as to foster interactions between communities and professionals. The central government is responsible for financing these small nuclei of health centers that can act as part of a broad national system that also provides other health care institutions for health needs that cannot be handled in these small nuclei (e.g. hospitals and rehabilitation centers).[28]

These small nuclei of health care centers or clinics open the doors to the local communities and promote their participation in the decision-making process to promote health and health care in particular realities; hence, they connect health care providers to people. This approach facilitates the identification of the most vulnerable citizens. Theological reflection challenges health workers and administrators to approach the people where they live.[29] Religious traditions are networks that join people and allow them to interact with each other by sharing their wisdom and being more involved in the political and social arena.[30]

Conclusion

Struggling against social unfairness and inequalities in health care to promote population health is a battle that must begin from below to be consistent, concrete, and democratic. The preferential option for the poor challenges us to join with the least of society and work with them to change structures of violence that are responsible for social unfairness and inequalities in health. By living with the poor, we recognize their power in history and their capacity to resist as well. The poor are not mere recipients of dominant knowledge; they have their own knowledge that helps them to keep going with faith and hope amidst their suffering. Dialogue builds a democratic participation that holds the possibility of transforming social reality. The dialogue between intellectual knowledge and the poor generates a new strength that encourages us to struggle against oppression and injustice.

Being with the poor in a humble action of creative dialogue and participatory construction of alternative ways, we recreate the world. Catholic social teaching is an open knowledge to dialogue with the poor in their *locus*. This dialogue is open to more agents, such as scientists, philosophers, and sociologists who help theological bioethics and the poor to understand the mechanisms of structural violence. Together with the poor, we struggle to transform society and promote social justice and justice in health care. In this dialogic relationship, we can build solid ways that promote social justice, a requirement for population health. At the same time, we support a public health system with universal assistance that works with other social sectors and

focus on primary care with participation of the local community in the decision-making process.

Endnotes

[1] Norman Daniels, *Just Health: Meeting Health Needs Fairly* (Cambridge – New York: Cambridge University Press, 2008): 6.

[2] Lisa S. Cahill, *Theological Bioethics: Participation, Justice and Change* (Washington, DC: Georgetown University Press, 2005): 1.

[3] Conferência Episcopal Latino Americana – CELAM, *Documento de Aparecida* (São Paulo; Brasilia: Paulus; Edições CNBB, 2007) no. 392.

[4] Gustavo Gutierrez, "Memory and Prophecy," in *The Option for the Poor in Christian Theology*, D. Groody, ed. (Notre Dame, Indiana: University of Notre Dame Press, 2007): 18.

[5] I would like to explain why I chose "justice in public health" as the title for this part rather than only "justice in health". Promoting justice in health, in a way that addresses both local and global population health, requires a robust public health system. This system should be universal and has as a starting point a broad and efficient web of primary care that focuses on health education, prevention, and early diagnosis (See World Health Organization, *The World Health Report 2008: Primary Health Care*, available online at: http://www.who.int/whr/2008/en/index.html). The first goal of a public health system should be the promotion of population health rather than simply being curative. Primary care will shape the politics of allocation of resources in health. However, for a system like that to be fair and to work, it must be supported by just social structures and democratic participation.

[6] It is not necessary to provide a lot of dates as proof to find out that poverty is the number one cause that affects population health in the world. To see data, the World Health Organization provides annual reports about health in the world (available online at http://www.who.int/whr/en/) in which you can verify the connection between poverty and health. See also World Health Organization, *Closing the gap: Policy into practice on social determinants of health-Discussion Paper*, available online at: http://www.who.int/sdhconference/discussion_paper/en/

[7] See Simone Weil, *Attente de Dieu* (Paris: La Colombe, 1950): 130-135.

[8] Daniels, *Just Health,* 1. Mr. Daniels is a philosopher and bioethicist at Harvard University who has written about issues of justice in health care. He supports the view that a theory of justice is the first step to promote justice in health care.

[9] There are many theories of justice that have been formulated since Plato and Aristotle. I recognize the importance of these theories. I do not simply refuse them to replace them with the Catholic social tradition's theory of justice. Although, I refuse a theory of justice as a starting point because it risks creating a perfect society for imperfect human beings who live in problematic contexts. Instead, we need to begin from real, concrete circumstances, suffering, and needs.

[10] See Paul Farmer, *Pathologies of Power: Health, Human Rights, and the New War on the Poor* (Berkeley: University of California Press, 2003): 26, 146.

[11] Farmer, *Pathologies of Power*, 50.

[12] Farmer, *Pathologies of Power*, 27.

[13] This strategy configures a peaceful face of the neoliberal system and of the elites by showing them as charitable and kind. On the one hand, the goal seems to be keeping poor people calm and believing that if they are still miserable, it is their fault because the system is good. On the other hand, the system is actually exploiting them, supporting the status quo, and creating more poverty. This is the cruelest face of the neoliberal reformism and it fosters structural violence

[14] Amartya Sen writes that equity in health requires social arrangements that achieve fairness and justice. See Amartya Sen, "Why Health Equity?," in *Public Health, Ethics, and Equity*, Sudhinr Anand; Fabienne Peter; Amartya Sen, eds. (New York: Oxford University Press, 2004): 21.

[15] Sen, "Why Health Equity?," 22.

[16] Jon Sobrino, *Jesus, o Libertador*. 2nd ed. (Petrópolis: Vozes, 1996): 121.

[17] Thomas Aquinas affirms that the supreme good is God who is the creator of all goods. The good of all things depends on God. David Hollenbach says: "The good of each person is linked with the good shared with others in the community, and the highest good common to the life of all is God's own self." See David Hollenbach, *The Common Good and Christian Ethics* (Cambridge, MA: Cambridge University Press, 2002): 4.

[18] *Gaudium et Spes*, no. 26, in *Catholic Social Thought: The Documentary Heritage,* O'Brien, David J., Shannon, Thomas A., eds. (Maryknoll, NY: Orbis, 2010).

[19] Paul VI. *Populorum Progressio*, nos. 14-21, in O'Brien, David J., Shannon, Thomas A., eds. *op. cit.*

[20] Hollenbach, *The Common Good and Christian Ethics,* 192.

[21] John Paul II. *Sollicitudo Rei Socialis*, no. 38, in O'Brien, David J.; Shannon, Thomas A., eds. *op. cit*.

[22] See Pontifical Council for Justice and Peace, *Compendium of the Social Doctrine of the Church,* (Washington, D.C.: Libreria Editrice Vaticana, 2004): no. 201.

[23] Hollenbach, *The Common Good and Christian Ethics,* 198.

[24] Lisa S. Cahill, *Bioethics and the Common Good,* (Milwaukee: Marquette University Press, 2004): 10.

[25] See Paulo Freire, *Education for Critical Consciousness*, (New York: Continuum, 2005): 3-5.

[26] Farmer, *Pathologies of Power*, 140.

[27] Farmer, *Pathologies of Power,* 162, 165.

[28] This is an experience of Brazilian Public Healthcare System that has given good results. See Associação Paulista de Medicina, *SUS: O Que Você Precisa Saber Sobre o Sistema Único de Saúde*, (São Paulo: Atheneu, 2010).

[29] Lisa S. Cahill says: "Structures and networks are developing locally and globally through which the participation of the poor and of those in solidarity with them is becoming more effective." See Lisa S. Cahill, *Bioethics and the Common Good*, 77.

[30] The experience of basic Christian communities (CEBs) in Brazil has permitted the development of a social

ministry (*Pastoral Sociais*) that created Pastoral of Health. Pastoral of Health spread throughout the whole country in parishes and CEBs and has helped to empower people who have worked to build the Brazilian Public Health System that offers universal assistance. See Conferência Nacional dos Bispos do Brasil, *Fraternidade e Saúde Pública: Que a Saúde se Difunda Sobre a Terra*, (Brasília: Edições CNBB, 2011).

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FEATURE ARTICLE

Palliative Sedation: A Review of the Ethical Debate

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Editor's Note: The author of this article, Joseph A. Raho, has just completed his doctoral work in philosophical bioethics at the University of Pisa, Pisa, Italy. His dissertation and several of his publications are on palliative sedation.

Introduction

Despite state-of-the-art palliative care, there may be rare instances in which distressing symptoms persist. Within this context, an ethical discussion has taken place concerning the use of sedatives. *Palliative sedation* may be defined as "[...] the monitored use of medications intended to induce a state of decreased or absent awareness (unconsciousness) in order to relieve the burden of otherwise intractable suffering [...]" (Cherny and Radbruch 2009, p. 581). After more than twenty years of research and discussion, this practice remains ethically charged. Under what circumstances might sedation be a morally appropriate intervention? After situating the debate, clarifying the clinical and ethical indications for commencing sedation, and reviewing problematic aspects, I will argue that palliative sedation may be an ethically appropriate option in certain well-defined situations of last-resort. Central to the ethical evaluation of the practice is the *principle of proportionality*.

Situating the Debate

Recourse to sedation for the palliation of refractory symptoms was first described as an emerging (and potentially problematic) practice in an early Italian study (Ventafridda *et al.* 1990). One year later, the expression *terminal sedation* was coined to refer to "sedation-induced unconsciousness" in order to relieve uncontrolled symptoms (Enck 1991, p. 5). This terminology, although widely used, is ambiguous, leading many health professionals to wonder whether palliative sedation aims exclusively at symptom relief or whether it might constitute *slow euthanasia* or *euthanasia in disguise*, especially when artificial nutrition and hydration (ANH) are withheld (see Billings and Block 1996; Tännsjö 2004).

In recent years, international studies (both retrospective and prospective in design) have cast some light on clinical practice, although large divergences remain both within and among countries concerning the frequency of palliative sedation.[1] Comparative research from six European countries found that, among all deaths in 2001, *continuous deep sedation* (CDS) was

resorted to in 2.5 percent of cases in Denmark, whereas the percentages were 5.7 in the Netherlands, 8.2 in Belgium, and even 8.5 in Italy (Miccinesi *et al.* 2006). This study also revealed that CDS was performed without ANH in 35 to 64 percent of cases. The frequency of sedation has also increased in recent years. CDS in the Netherlands, previously estimated at 5.7 percent of all deaths, grew to 7.1 percent by 2005 (Rietjens *et al.* 2008) and even 12.3 percent by 2010 (Onwuteaka-Philipsen *et al.* 2012). In Belgium, CDS increased from 8.2 percent to 14.5 percent by 2007 (Chambaere *et al.* 2010). And data from the U.K. indicates that CDS is as high as 16.5 percent (Seale 2009).

Such frequencies suggest that palliative sedation may no longer be a measure of last resort. Might physicians be using sedation when other less-aggressive options remain available? Does the use of sedation circumvent attempts to provide intensive caring at life's end? If sedation is administered without ANH, are patients' deaths being hastened? How might one draw a distinction between palliative sedation and euthanasia or physician-assisted suicide?

Palliative Sedation: Consensus and Contestations

Sedation is used in a variety of palliative care contexts—*e.g.*, in trauma and burn care, as well as during ventilatory withdrawal. In the end-of-life setting, it is generally indicated for patients who experience intolerable distress from symptoms that have proven refractory to traditional palliative interventions. Palliative sedation may be administered either intermittently or continuously, and its intensity may be either mild or deep (Morita *et al.* 2002).[2]

Since the early position statement by Quill and Byock (2000), many professional guidelines on palliative sedation have been published.[3] Although some differences are evident, a professional "consensus," however tentative, has emerged. Palliative sedation is generally considered clinically indicated and ethically permissible only in certain rare circumstances. Patients must be (1) terminally ill, (2) imminently dying, and (3) suffering from one or more refractory symptoms. Moreover, CDS should only be attempted when (4) either intermittent or respite sedation has been unsuccessful in reducing the severity of the refractory symptom (5) within an acceptable time frame. In addition to these criteria, informed consent must be obtained from the patient (or surrogate). Finally, the decision to continue or discontinue ANH is usually considered to be a separate decision.[4]

Let us briefly clarify these points. Concerning the terminality condition, patients must be in the final stages of a "*severe, chronic, life-threatening illness*" (Krakauer and Quinn 2010, p. 1563; emphasis in original). Regarding the imminence condition, death will be expected to occur within a very short time, usually measured in hours or days (according to the EAPC) or, at most, two weeks (according to the RDMA and the NHPCO). Furthermore, refractory symptoms are to be distinguished from

difficult-to-manage symptoms. Common refractory symptoms include delirium, dyspnea, pain, and fatigue. Krakauer and Quinn (2010, p. 1560) state that "[s]uffering is refractory when it cannot be adequately relieved despite aggressive and concerted efforts both to determine its causes and to treat them using standard palliative interventions without inducing sedation." Cherny and Portenoy (1994) also include in this category those therapies that are associated with excessive or unacceptable morbidity. CDS should only be offered when intermittent or respite sedation has failed to reduce the suffering associated with the refractory symptom. Intermittent sedation allows for periods of alertness and respite sedation is "time-limited." These types of sedation are believed to offer short-term relief from discomfort and may be used even earlier in the patient's disease trajectory (Cherny and Radbruch 2009, p. 584). If traditional palliative measures are unlikely to provide relief within a reasonable time frame, the symptom may be considered refractory.[5] Finally, ANH is considered to be a separate decision. As Claessens *et al.* (2008. p. 329) have argued, "If a patient shows signs of imminent death (*e.g.*, loss of appetite, decreased food/fluid intake) before sedation, then it seems irresponsible and unethical to hamper the natural dying process by administering artificial food or fluid during sedation." When provided during the final three weeks of life, the associated risks of medically assisted hydration include "[...] exacerbation of oedema, ascites and pleural effusions" and there may be "[...] no improvement in the level of confusion or the ability to communicate" (Sykes 2013, p. 97; reference omitted). In light of these issues, the benefits and burdens of providing ANH should be assessed on their own basis, independent of the decision to begin sedation.

Aspects of this consensus have been contested, however. With regard to the imminence condition, physicians often have difficulty prognosticating (Swart *et al.* 2014, p. 28) and when death is not imminent—*i.e.*, anticipated within hours—estimating life expectancy can be difficult, perhaps even impossible (van Delden 2013, p. 221). The guidelines in the Netherlands permit palliative sedation without ANH when death is expected within two weeks. The idea here is that a patient will not die from dehydration. However, this presumption may be questioned: although death from dehydration usually occurs after about two weeks, patients who receive palliative sedation are seriously ill and have sub-optimal hydration status. As van Delden (2013, p. 221) points out, "[...] accepting a two-week limit actually means accepting that the moment of death of at least *some* patients will be determined by the dehydration that comes with continuous sedation (without ANH) and not by the underlying disease."

For sedation to be clinically indicated, symptoms must be refractory—not merely difficult-to-manage.[6] There are a couple of problems here. First, as Sterckx *et al.* (2013, p. 14) note, "[...] what defines refractoriness is not the nature of a symptom, but *how* one may fail to treat it." For example, treatments might be available, but take too long to become

effective. Sometimes treatments that are readily available in one setting (*e.g.*, a hospital) may be unavailable in another (*e.g.*, at home). Also, physicians may lack expertise, and hence conclude too quickly that the symptom is refractory when other less-aggressive options exist. Second, the experience of suffering is inescapably subjective. If this is granted, how can physicians determine whether a particular symptom is refractory? A case can be made that only patients can determine whether a symptom is intolerable—physicians, for their part, must assess whether a given treatment will respond to that distress. This means, however, that decision-making authority effectively shifts from the physician to the patient. May patients request deep and continuous palliative sedation in the absence of first having tried mild or deep intermittent sedation? Is it also morally licit to do so while withholding ANH?

Ethical Analysis

The principles of *beneficence* and *non-maleficence* occupy a central place in discussions of medical ethics. Simply stated, physicians should benefit patients and not bring harm to them. However, palliative sedation is controversial. There are a number of anticipated adverse outcomes and potential complications associated with the practice—including respiratory depression, aspiration, hemodynamic compromise, paradoxical agitation, as well as hastening of death (Cherny 2009, p. 1153; Cherny and Radbruch 2009, p. 582). Moreover, reducing a patient's consciousness is a far-reaching intervention. Although mild levels of sedation will allow for interaction with family, friends, and caregivers, deeper levels will not. Human consciousness is a human good, and many patients and families value mental awareness during life's final moments (Steinhauser *et al.* 2000). Thus, at a minimum, human consciousness should not be taken away, except under valid moral reasons. This point is underscored in a recent statement by the International Association of Catholic Bioethicists (2012, p. 497):

Consciousness is integral to human flourishing and remains a good for persons who are seriously ill or dying. Thus care providers should protect and promote unclouded consciousness in patients whenever possible, especially to allow them to prepare for death. Care providers should suppress consciousness beyond the natural wake-sleep cycles only for very serious reasons.

In the literature, numerous authors cite the *doctrine of double effect* (DDE) as important to the ethical analysis of palliative sedation. Central to this discussion is the intention of the moral agent; physicians should aim exclusively at the relief of suffering, not the hastening of death (even though the latter may result as a foreseen, unintended result). This strategy, however, has not been beyond dispute. Critics charge that the doctrine's reliance on the intention of physicians is problematic, as intentions can be "complex, ambiguous, and often contradictory" (Quill 1993, p. 1039). Others assert that the loss of consciousness engendered by palliative sedation is not simply unintended; instead, it is the

means by which symptoms become controlled (Raus, Sterckx, and Mortier 2013, pp. 189-190). This contradicts one central criterion of the DDE, since the bad effect (loss of consciousness) is the means to the good effect (symptom relief).

Although the DDE plays an important role in discussions of end-of-life care, I would suggest that an alternative principle—that of *proportionality*—is really at the heart of the ethics of palliative sedation. To recall the distinctions outlined earlier: palliative sedation may be administered intermittently or continuously, and its intensity may be mild or deep. When considering CDS, intermittent (either mild or deep) sedation should be tried first. However, in the case of a catastrophic emergency—such as massive haemorrhage, asphyxiation, severe terminal dyspnea or overwhelming pain crisis (Cherny and Radbruch 2009, p. 584)—CDS may be needed from the start, even if such instances are likely to be rare (de Graeff and Dean 2007, p. 74).

Following these distinctions, palliative sedation refers to a spectrum of therapeutic interventions aimed at reducing the severity of a refractory symptom. Central is the notion of symptom control. Sedatives should be titrated to effect and there should not be a presumption in favor of causing rapid unconsciousness. As explained by Sykes (2013, p. 95), "[...] relief of distress is the endpoint, not a particular level of consciousness." The aim of sedation is not to cause more harm than necessary, which means that there should be a correspondence between the symptom and the way it becomes controlled. One way to verify this is to place notations in the medical record. As De Graeff and Dean (2007, p. 70) relate, "Repeated doses, titrated to ease an individual's distress, are the mark of proportionate sedation. Single large doses are the mark of ignorance or intentional harm." Consciousness should be maintained whenever possible, although some clinical circumstances and patients' preferences will require deeper levels of sedation. As the need for targeted relief may evolve during their clinical trajectory, it is an open question whether patients will receive deeper forms of sedation. CDS, the most extreme form, should be reserved for true situations of last resort.

These points also help us to distinguish palliative sedation from euthanasia and physician-assisted suicide. With the latter practices, no titration is involved, as the death of the patient is their immediate goal. With palliative sedation by contrast, "[...] the death of the patient is not a criterion for the success of the treatment […]" (de Graeff and Dean 2007, p. 76). Moreover, whereas patients who request euthanasia and physician-assisted suicide have a terminal illness, many are not imminently dying (as previously defined). One study found that "[...] patients who are terminally sedated are generally sicker and closer to death than patients receiving euthanasia" (Rietjens *et al.* 2006, p. 752). One might counter that sedatives provided in high enough doses will cause respiratory depression and precipitate death. Even if this is granted, the potential life-shortening effects of palliative sedation have not been confirmed by recent

research.[7] Again, the ethical core of palliative sedation is the notion of proportionality; all interventions short of compromising consciousness should have been offered before resorting to palliative sedation.

Conclusion

Palliative sedation, although controversial, remains an important clinical intervention for select patients at the end of life. In recent years, a tentative professional consensus has emerged. Before considering this intervention, a number of clinical and ethical criteria should be satisfied. Patients must be (1) terminally ill, (2) imminently dying, and (3) suffering from one or more refractory symptoms. CDS should only be attempted when (4) either intermittent or respite sedation has been unsuccessful in reducing the severity of the refractory symptom (5) within an acceptable time frame. Proportionality is crucial to the ethics of this practice. The purpose of palliative sedation is to respond to a symptom refractory to state-of-the-art palliative interventions. Clinicians should begin generally with the lowest level of sedation and increase its depth only as much as necessary to control the refractory symptom. As some circumstances will require lesser amounts of sedatives, others may require more. It is therefore an open question whether resorting to CDS will be required from the start. This highlights the importance of working case-by-case. In providing holistic care at the end of life, palliative medicine should be well-positioned to meet this challenge.

NOTES

1. For two literature reviews, see de Graeff and Dean (2007) and Claessens *et al.* (2008). For a more recent review, see Bruinsma *et al.* (2013).

2. Whereas mild sedation aims "to maintain consciousness so that patients can communicate with caregivers," deep sedation aims "to achieve almost or complete unconsciousness." Similarly, intermittent sedation aims "to provide some periods when patients are alert," whereas continuous sedation aims "to continue to alter patient consciousness until death." Morita *et al.* (2002, p. 450).

3. See the guidelines of the Veterans Health Administration (VHA) (National Ethics Committee 2007), the American Medical Association (AMA) (Council on Ethical and Judicial Affairs 2008), the European Association for Palliative Care (EAPC) (Cherny and Radbruch 2009), the National Hospice and Palliative Care Organization (NHPCO) (Kirk and Mahon 2010), and the national guideline of the Royal Dutch Medical Association (RDMA 2009) in the Netherlands (which has legal ramifications in that country).

4. The guidelines of the VHA, AMA, EAPC, and NHPCO support this position.

5. Consider the following example: some treatments—*e.g.*, for clinical depression—require more than two weeks of therapy in order to have a satisfactory result. If a patient has a prognosis of death estimated at one week, pharmacotherapy is unlikely to be effective, and therefore depression would be considered refractory. See Wilson *et al.* (2000 p. 38).

6. If sedation is used for a symptom that is merely of the latter sort, it is considered either an "abuse" or "injudicious use" of sedation. See Cherny and Radbruch (2009, p. 582).

7. On this point, see Sykes and Thorns (2003); Maltoni *et al.* (2009); and Sykes (2013, pp. 95-96).

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CDF Principles for Collaboration with Non-Catholic Health Care Entities: Ministry Perspectives

Editor's Note: On February 17, 2014, the Congregation for the Doctrine of the Faith, under the signature of Cardinal Mueller, issued a reply (but not an official responsum) to a question that it had received from the USCCB in April, 2013. The question had to do with whether a Catholic health care system could become non-Catholic. While the CDF did not directly respond to the question, seeing it as a concrete application of established moral principles, it did forward to the USCCB a set of seventeen principles to guide the forming of partnerships with non-Catholic organizations. The principles were intended to be of assistance to the bishops of the United States. While awaiting comment on the principles by the USCCB, we include here several reflections on the principles from ethicists in or associated with Catholic health care. Contributors were asked to reflect on 1) Is there anything new in the principles? If yes, what? And what are the implications of that for Catholic health care? 2) If no, then how can this document be helpful in forming partnerships? What effects might it have on forming future partnerships?

It should be noted that the reply of the CDF to the dubium is not a typical "responsum." The principles do not appear on CDF stationary, the format is not that of a typical responsum, they are not signed by the Prefect and the Secretary of the CDF, they are not dated, nor is there any indication that the principles were seen by or approved by the Holy Father.

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Answering the question as to whether *Some Principles for Collaboration with Non-Catholic Entities in the Provision of Healthcare Services* by the Congregation for the Doctrine of the Faith contains anything new depends on to what the document is being compared. When compared internally to previous magisterial statements pertaining to the Principle of Cooperation, it represents a development in the sense that for the first time a delineated set of specific principles pertaining to the institutional application of the traditional Principle of Cooperation in evil is offered.[1] In this regard, there is much that is new in the document. With respect to the wider context of Catholic/other-than-Catholic health care collaboration, its content is more confirmatory than new. However, these facts are important because by confirming recent interpretations and applications of the Principle of Cooperation to collaborative efforts, the CDF *Principles* provide invaluable guidance. This guidance is evident both in what the document says and in what it does not prohibit.[2]

Specifically, the CDF document confirms that financial viability need not be the only morally legitimate reason to engage in mediate material cooperation. It also confirms the moral legitimacy of Catholic and other-than-Catholic partners being in the same health care system, including a system with a Catholic parent. Moreover, there is no prohibition of Catholic institutions participating in for-profit systems, even if the Catholic subsidiary has no role in the governance of the system. Thus, based on the content of the *Principles*, for-profit status by itself does not seem to constitute illicit cooperation, nor does it preclude the possibility of preserving Catholic identity. It also confirms the moral legitimacy of individuals from Catholic organizations serving on boards of systems that include other-than-Catholic facilities.[3] An examination of the Prologue and some of the principles in the CDF's document will show how these points are confirmed in the document.

The Prologue is important because it confirms that the obligation to collaborate with others in charity and the Principle of Cooperation are distinct but correlative principles. Often times we need to collaborate with others in fulfilling the call to love our neighbor. This is no less true in the ministry of health care. The prologue states that ". . . effective engagement in healthcare often calls for collaboration with non-Catholic healthcare institutions, even establishing joint working arrangements in which the Catholic and non-Catholic entities are full partners. In itself, collaboration in good works is of course, a good thing . . . ." This truth lays the foundation for using improved service to the health care needs of the community as a sufficient reason justifying mediate material cooperation.

The first principle addresses the fundamental question as to whether the traditional Principle of Cooperation may apply to institutions, which is answered in the affirmative. The CDF indicates that institutions do have moral agency and therefore can cooperate in the wrongdoing of others.[4] However, the moral agency exercised by corporations is analogous to the agency of natural persons. Institutions have an identity and character, but this is caused by the decisions of natural persons. Thus, this principle emphasizes the importance of individual decision-making being consistent with Catholic teaching since those decisions determine the moral status of institutional cooperation.

That Catholic institutions do not engage in illicit cooperation simply by participating in a system with other-than-Catholic entities is evident from the fact that the *Principles* only prohibit certain kinds of activity by the Catholic partner, not the participation itself. This implicit recognition is found in most of the principles articulated by the CDF. In the terms of the *Principles*, those decisions of an administrator are prohibited that have a "close connection" to immoral actions, are "involved directly" in or are "proximately connected" to such procedures, that carry an official consent to immoral procedures, or that "enter into" the very essence of the principal act. This prohibition points to the issue of how the nature of the work of administrators factors into a cooperation analysis of partnerships. It shows that the nature of their work does not

per se involve illicit cooperation, but only specific decisions that have a strict correlation between the content of the decision and the affected principal action (see *Principles*, ns. 1, 3, 4, 9, and 11).

The *Principles* indicate that ownership in a system that includes other-than-Catholic institutions is not by itself morally decisive, but rather the nature of the reserve powers and the decisions that the board members make is. The nature of their work pertains to global matters of the organization such as broad policy, strategic issues, global budgeting, and contractual agreements. Further evidence that a Catholic institution in a mixed system does not constitute illicit cooperation is the fact that the *Principles* allow Catholic institutions to hold "seats" on the boards of such systems, the requirements of civil law notwithstanding (*Principles*, n.11). Moreover, the *Principles* recommend recusal in appropriate situations precisely in order to allow for the continued service of Catholic representatives on system boards while avoiding illicit cooperation (*Principles*, n. 11). This means that recusal is not itself evidence that service on such boards is *per se* illicit, and it means that there is no obligation for the Catholic parties to object in every case of a supposed connection to immoral activity in order to avoid illicit cooperation.

At first glance, Principle 5 could appear to make the real risk of financial viability the only reason for mediate material cooperation, which would exclude the preservation of financial stability as a reason. However, the principle is constructed as a condition. It states that if a financial reason for cooperation is cited, it should not be financial advantage or financial stability for its own sake but grave financial pressure. This does not mean that better service to the needs of the community is excluded as a sufficient reason for material cooperation, nor does it mean that preserving current financial stability is excluded as a reason when market analysis shows that the institution will likely not be able to survive at some point in the near future unless it collaborates.

In order to understand and apply Principle 12 on setting up an independent body to oversee immoral activity, it is important to distinguish between the act of setting up an independent entity to oversee immoral procedures, and acknowledging what the Catholic parties cannot do. Establishing an independent board or committee includes actions such as drawing up its bylaws, legally incorporating the entity, and creating its policies and procedures. None of the activities of setting up the independent boards are included in what a Catholic party does. Furthermore, merely knowing that an other-than-Catholic partner will use the Catholic partner's avoidance of illicit cooperation as an occasion to establish an independent oversight board is not an intention for that entity and its purposes, nor does it constitute an act of helping to set up the entity. Foreseeing a result is not in itself evidence that the result is willed, intended, or desired. The proximate intention of the Catholic parties in this situation is to prevent illicit cooperation.

Although Principle 16 refers to Catholic institutions that are extricating themselves from situations of illicit cooperation, it implicitly recognizes the moral legitimacy of the concept of a Statement of Common

Value. A SCV is a set of principles that, for an other-than-Catholic entity, adheres as closely as possible to the principles of the natural moral law as it relates to health care. The fact that there are no restrictions regarding contraceptives and direct sterilization in a SCV does not entail an intention for such procedures on the part of the Catholic parties. The intention of the Catholic parties and the other-than-Catholic partner in requiring an SCV is specifically to ensure that the values of the system will adhere as closely as possible to the natural law. Moreover, the Catholic parties do not engage in implicit formal cooperation by deliberately omitting a prohibition against contraceptives and direct sterilization in a SCV, because this omission does not constitute a specific formal condition by which the performance of such activity is made possible. It is the other-than-Catholic parties that supply those conditions.

The CDF's *Principles* provides a helpful guide that is both consistent with the Catholic moral tradition on cooperation and confirms recent interpretation and application of the Principle of Cooperation to Catholic/other-than-Catholic health care collaborations. As such, it provides an important conceptual framework within which new collaborative relationships may be evaluated.

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[1]For example, the document goes beyond making brief (though important) reference to the principle as is found in documents such as *Quaecumque Sterilizatio*, n. 3 (On Sterilization in Catholic Hospitals) or in *The Gospel of Life* (n. 74). For a traditional account of the Principle of Cooperation, see John A. McHugh, O.P., and Charles J. Callan, O.P., *Moral Theology*: *A Complete Course*, rev. ed. (New York: Joseph F. Wagner, 1958).

[2]It is important to note that the term "cooperation" as it functions in the Principle of Cooperation pertains to an identifiable voluntary contribution to the wrongdoing of another and that its meaning is distinct from the meaning of "collaboration," which in the current context refers to a specific joint effort between and among health care providers.

[3]The *Principles* refer to "administrators," board members," board of directors," "directors," and "boards" without clearly distinguishing these terms. For the purposes of this commentary, "administrator" will be used to refer to board members and executives.

[4]For a brief overview of corporate moral agency and cooperation see Peter J. Cataldo, "State-Mandated Immoral Procedures in Catholic Facilities: How is Licit Compliance Possible?" in *Live the Truth*: *The Moral Legacy of John Paul II in Catholic Health Care*, ed. Edward J. Furton (Philadelphia: The National Catholic Bioethics Center, 2006): 258–261.

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The Congregation for the Doctrine of the Faith's (CDF) *Principles for Collaboration with Non-Catholic Entities in the Provision of Health Services* is a response to Cardinal Timothy Dolan's request (April 15, 2013) for assistance regarding the transformation of a Catholic health system into a non-Catholic health system. Of particular concern are the transactions of a Catholic health system with non-Catholic members and organizations that provide procedures that are non-compliant with the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs).

The prologue to the document provides a brief history of Catholic health care throughout the ages with a focus on today's challenging health care environment that is now calling for collaboration with non-

Catholic health care institutions. Depending on one's perspective, this can be good news—collaboration and good stewardship of resources, or bad news—the "diminution of the prophetic witness to the Faith" and the cause of scandal to the Church.

The CDF's *Principles* are meant to assist bishops and, indirectly, Catholic health care institutions in addressing this complex health care environment so that in such transactions, Catholic health care institutions neither cooperate immorally with procedures that are non-compliant with the ERDs nor cause scandal as a result of their collaboration. Principles #1-4 present the traditional definition of formal cooperation that could share intention or not in cooperating or contributing to the immoral acts.

Principle #5 is new from my perspective. In the past, duress was allowed primarily for individuals and not for Catholic institutions. Principle #5 allows for Catholic health care providers under duress or grave pressure to cooperate under certain conditions:
"In dealing with a Catholic healthcare institution that faces particular concrete circumstances involving its ability to continue its ministry at all, in order for material cooperation in such an institution to be moral, besides meeting the other relevant criteria, the institution must be under grave pressure to cooperate. Considerations of financial advantage or even of financial stability do not constitute sufficiently grave pressure; considerations having to do with the financial viability—that is, the ability of the healthcare institution to survive and to carry out its mission in the face of the complex circumstances that are present locally—do." (Principle #5)

Given the current U.S. health care environment, this is an important development. In addition to concerns regarding financial viability, I would submit that there are also concerns of grave pressure from adverse market forces that could put a Catholic health care institution's viability, while not imminent, in serious jeopardy in the future.

Principles #6-15 underscore the point that the Catholic health care entity cannot govern, manage, perform or contribute to the direct performance nor financially profit from the procedures that are non-compliant with Church teaching. These are basic, elemental moral principles. Furthermore, the Catholic entity cannot set up or help set up an entity that would be engaged in procedures that are inconsistent with Church teaching. Catholic Health Initiatives (CHI) makes it clear from the start of a transaction that if such an entity is to be created, it is up to the future partner to make those arrangements beforehand, without any involvement from CHI.

Principle #17 requires that diocesan bishops be informed of prospective agreements in Catholic institutions. For many systems, this may mean notifying a number of bishops. For those who are public juridic persons, they do not have to get permission, but rather a "nihil obstat."

In conclusion, the CDF's *Principles* seem to be principles that have generally guided transactions between Catholic and other-than-Catholic health care entities. It will remain to be seen how people interpret and apply Principle #5 that could involve grave pressure

that affects survivability of a Catholic health care provider.

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On February 17th, the Congregation for the Doctrine of the Faith, under the signature of Cardinal Müller, responded to a question, a *dubium*, posed to the Congregation by Cardinal Dolan in the name of the United States Conference of Catholic Bishops (USCCB). The core issue presented to the Congregation pertained to "the transformation of a Catholic system into a non-Catholic system." The question that, in all likelihood, was puzzling to Cardinal Dolan and the other Catholic bishops was the transformation of Catholic Health West into Dignity Health. An even more precise statement of the *dubium* would express the bishops' concern regarding the status of a Catholic health care system that included non-Catholic members, who do not comply with the prohibition of morally unacceptable practices such as sterilization and contraception.

The Congregation's response is out of character compared to other such documents. Cardinal Müller signals as much in his cover letter in which he states that, "it is not possible to respond to the *dubium* in the usual manner." The *dubium*, Cardinal Müller proposes, "concerns more the application of moral principles to concrete situations and less an articulation or clarification of the operative moral principles." But then the reply goes on not to speak about the application of moral principles, but rather proposes 17 new principles that are supposedly relevant to the issue raised by the *dubium,* but says nothing regarding the application of the principles to the case.

The appearance of these 17 principles as the substance of the reply is a cause of wonderment, and even concern, that perhaps they are the introduction of novelty into Church teaching. Where did these principles come from? What is their origin? What is their "sitz im leben" with regard to the life of the Church and tradition? The principles are presented as a list. There is not one footnote or reference to document the teaching associated with these principles, nor are there references to link them to prior Church teaching or the tradition. There are neither references to Scripture nor to the papal magisterium. Where do these principles come from? There is nothing to suggest that the principles are related to the writings of any current or former theologians. There is no indication that the Holy Father reviewed, much less endorsed, the principles. They are new, they are innovations, and, like any innovation in Church teaching, they need to be treated with a high degree of skepticism until their link to the authentic magisterium can be verified. But the mystery remains, from where did these principles come? Is it possible that "the voice is that of Jacob, but the arms are those of Esau?"

The reply to the *dubium* leaves the USCCB in a conundrum. First, it provides no remedy or guidance regarding the application of moral principles to concrete cases. That was the question posed by the USCCB. Second, how, in what ways and on what grounds are the

bishops to incorporate such novel teaching into their own teaching office? Do they simply accept it because it comes from Rome? Or do they need to question it and determine its origin in Scripture, tradition or the teaching office of the papal magisterium? If individuals outside the episcopal teaching office were to influence the content of documents emanating from the Congregation for the Doctrine of the Faith when responding to questions posed by the USCCB, if this happens to be the case, where does that leave the integrity of the teaching office of the American bishops or why appeal to Rome for guidance?

Finally, what about the principles themselves? It would be tedious to comment on each of them, so for the purposes of this essay, let me focus simply on the first. The issue at stake in this principle is the moral agency of Catholic health care institutions. The principle maintains that the only relevant moral agency is that of CEOs, trustees and other senior leaders. Cooperation is "ultimately about the actions of individual human beings." This position rejects any moral agency attributed to institutions themselves. It posits a negative response to the question: are large complex social institutions such as hospitals and health systems themselves moral agents? An affirmative answer to this question was recently expressed in an article in *Commonweal (Robert Osborn, "*Just War Illusions*," March 21,2014, p.10): "*The president is as incapable of fundamentally altering the character of an empire as the well-meaning CEO of an oil company is capable of turning the corporation - through token philanthropy and gestures of social consciousness, welcome though these may be - into something other than a competitive, extractive, self-interested, and profit maximizing system."

What is at stake here is crucial for the proper use of the Principle of Cooperation in the present health care delivery environment. A hospital is a complex social organization defined by systems of accreditation and licensure, by the conditions of participation established by CMS, as well as the various medical specialty boards. The essence of a hospital, so to speak, is a social and cultural construct. It can be and do only what its socially constructed nature enables it to be and do. Complex social institutions have no final end; their proper goal or good lies within the common good of a community. If the realities of what hospitals and health systems are, are to be assimilated into theological discourse, then such terms must be construed as general theological categories, i.e., categories shared by theology, but adopted from public discourse. General theological categories need to be distinguished from special theological categories that arise solely within theological discourse and whose meanings are defined by theological discourse. (Bernard Lonergan, *Method in Theology, 285-293).* Only from a theological perspective such as Catholic social teaching can the Principle of Cooperation be applied appropriately to complex social institutions. Only such institutions, not the CEO, trustees or senior leaders, are blessed with Catholic identity.

Perhaps there is a learning that all of us can take away from this response to the *dubium*. In *Evangelii Gaudium* (#16), Pope Francis stated:

> "Nor do I believe that the papal magisterium should be expected to offer a definitive or complete word on every question which affects the Church and the world. It is not advisable for the Pope to take the place of local bishops in the discernment of every issue which arises in their territory."

The issue posed by the *dubium* is a uniquely American issue. It is an important and more than valid question. But it needs to be discussed, debated and resolved by American theologians, representatives of the Catholic health care systems and members of the American hierarchy. Such a conversation needs to begin with the question the bishops posed to the Congregation, not with the 17 principles.

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It was over 20 years ago when the Catholic Health Association began an internal discussion about the relevance and correct application of the Principle of Cooperation to the emerging practice of Catholic health care institutions entering into various types of business arrangements with other-than-Catholic institutions. In the light of those and other internal discussions, as well as dialogue with the Congregation for the Doctrine of the Faith (CDF), the USCCB and numerous diocesan bishops, the most recent "Responsum" with its attached *Principles* is remarkable for several reasons.

First, the *Principles* affirm that "effective engagement in health care often calls for collaboration with non-Catholic entities even establishing joint working arrangements in which Catholic and non-Catholic entities are full partners." (Preamble) This is quite a shift from the suspicions, if not outright hostility, with which such arrangements were greeted in the 90s. Second, the very nature of the response, that it provides principles rather than concrete or specific conclusions, is a welcome development. *Principles* offer the ministry the "space" needed to explore various forms of business arrangements because, as the text notes, "…each concrete manifestation of a working relationship involving Catholic and non-Catholic healthcare institutions cannot be anticipated." (Preamble)

The *Principles* also are in clear continuity with previous CDF interventions when they affirm that the category of immediate material cooperation, which had been proposed as at times being licit, in fact is formal cooperation. (#2). The text also affirms the long held consensus among many moralists that a Catholic board member cannot vote to affirm ethical guidelines for a wholly owned non-Catholic institution that would permit direct sterilizations (a.k.a. "ERDs Lite") when it says "…this is likely an instance of formal cooperation" (#4) (It should be noted that the use of the word *likely* requires further ethical reflection.)

The *Principles* do raise several points that require further theological reflection and perhaps engagement with the USCCB Committee on Doctrine. In #5 the response seems to severely limit the application of the Principle of Cooperation to situations in which "…the ability of the institution to

survive and carry out its mission" is at risk. Financial stability or advantage is no longer relevant. Unfortunately there is no explanation for this narrowed range of application. I fear this restrictive understanding of "grave pressure" does not take into account the dynamic transformational nature of the changing landscape of health care delivery in the United States. Catholic health care institutions and systems that wait until their immediate future is at risk (as it would seem the text suggests) most likely will not survive the shift. It is to be hoped that long term survival challenges in today's dynamic market will be understood to constitute "grave pressure".

Another area requiring further reflection is how the *Principles* seek to distance a Catholic entity, and its administrators/board members, from the provision of illicit services. Popularly known as "carve outs" these entities have been a critical aspect of negotiating with non-Catholic institutions and communities. These entities that provide illicit services outside of the Catholic institution have been considered licit if they meet the threefold test of "no governance, no management, no profit" on the part of the Catholic entity. The *Principles* seem to propose a new requirement: "no influence" (#13). Most likely there will be a great deal of discussion about what is meant by "no influence". Some arrangements such as "mirror boards", much like immediate material cooperation, might be found to be a distinction without a basis in fact. The influence in such a situation is so powerful that it is the same as control since the whole logic of having mirror boards is to ensure integrated governance over legally distinct entities. But what about accountable care organizations and other evolving arrangements put together to assume the risk of providing health care for a defined population. Such arrangements will not survive without a bond of shared influence among a range of actors. Is this influence so distant from the object of the moral evil that it is licit?

A final concern is #17. If one follows the usual rules of canonical interpretation, I would suggest there is nothing new here. If a system is entering into an arrangement that will directly impact the character and identity of all of its institutions, then, much like the formation of a PJP, all diocesan bishops involved should be consulted. I say that because of the nature of the *dubium* which occasioned the *Principles*. If, however, the arrangement is specific to one institution in a particular church, and has no impact on the other institutions in the system, it is difficult to understand the canonical standing of any other diocesan bishop on this matter.

Hopefully the discussion and theological reflection that this document is prompting will advance Catholic health care's fidelity to its core mission as well as provide guidance for successfully navigating its significant challenges.

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One could summarize the Congregation for the Doctrine of the Faith's (CDF's) "Some Principles for Collaboration…" by saying that the document addresses the traditional

Principle of Cooperation (PoC), but articulates it in a new health care context.[1] It expresses important considerations for Catholic health care, which increasingly collaborates within new health care paradigms, such as accountable care organizations and clinically integrated networks. "Some Principles'…" attention and specificity to executive decision-making groups (e.g., boards, administrators) and organizational structures and strategic arrangements (e.g., governance, administration, operations) differentiate it from many other general and applied articulations of the PoC in health care.[2] It mentions executive groups and strategic arrangements in at least 14 of the 17 principles, giving flesh to the *Ethical and Religious Directives' (ERDs)* Part Six introduction encouraging "systematic and objective moral analysis" to new partnership.[3]

This level of PoC structure and process at administrative and board levels may be new to some Catholic health care organizations contemplating prospective transactions. Principles 4, 5, and 11 detail organizational/system structures mainly, while principles 7, 9, 12, and 13 particularize organizational/system processes. (Some crossover may exist, meaning that some principles describe both process and structure.) For the Catholic organization, due diligence in negotiations with other-than-Catholic systems requires art and science (i.e., attention to detail). Examples of "Some Principles'…" specificity are principles 12 and 13. There is moral significance and difference between two kinds of actions. On the one hand, Catholic organizations can communicate that they cannot take part in illicit procedures and presumably agree to an arrangement (i.e. third-party entity or structure) with sufficient moral distance (mediate material cooperation). On the other hand, Catholic organizations cannot 'lead the charge' to form that third-party entity or structure because this exemplifies the intention to perpetuate the immoral procedures by any other name (implicit formal cooperation).[4]

In my view, there are at least three main implications for Catholic health care. First, Catholic health care organizations must be intentional about these PoC deliberations. Some organizations may increase their vigilance. Others may add these considerations to their current level of awareness. Either way, a method of fostering awareness and purpose is to assimilate the principles into organizational resources and procedures. One could accomplish this a few different ways. One is to include experienced human resources – a mission leader, ethicist, moral theologian, and/or consultant with expertise in the PoC – to prospective transaction teams. A second is to add a section to mission discernment or mission-based decision-making processes about executive groups and strategic arrangements while discerning new partnership opportunities. Due diligence considerations and checklists may already include *ERD*-related items (if not, they should). A third is that "Some Principles…" could be transformed into a series of questions, analogous to the PoC "reflective process" questions in "Cooperating with Philanthropic Organizations" by Ron Hamel and Michael Panicola or the Discernment Guide in

Resources about The Principle of Cooperation by CHA.[5]

Second, this is an opportunity to reflect upon, dialogue, and discuss the *Principles* and the PoC, not only with our bishops and their advisors, but also within our organizations, especially with our leadership and boards. This process begins with reading the *Principles* and then self-reflecting. How do I process this? Group discussions could use hypothetical scenarios, actual past or existing scenarios, as well as current prospective partnerships. Using the example from the previous paragraph, group members may disagree about precisely what actions depict intent (explicit formal cooperation), or intent by any other name (implicit formal cooperation), with wrongdoing in a series of possible responses to a proposed transaction. Such disagreements reflect the tension, even in executive groups and with strategic arrangements, between the PoC's theological foundations of discipleship and integrity.[6] These tensions are unlikely to dissipate and, as such, they are "polarities to manage."[7] Disagreements are also useful because they are formative and may even foster our moral development.[8]

Third, we can rejoice! Applying the *Principles* may be challenging. It also may be an example of the tough work Pope Francis explains in *Evangelii Gaudium*. Our Christian and Catholic witness is to find a way, reunite and bridge-build, and dialogue, even with those who differ from us ideologically and practically.[9] "Some Principles…" *is* itself a sign of the witness and flourishing of Catholic health care now and into the future. Our uses of, applications of, and communication and dialogue about "Some Principles…" *are* likewise.

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[1] Congregation for the Doctrine of the Faith (CDF), "Some Principles for Collaboration with Non-Catholic Entities in the Provision of Healthcare Services" (Vatican: Congregation for the Doctrine of the Faith, February 17, 2014).

[2] See, for instance: Catholic Health Association (CHA), *Report on a Theological Dialogue on the Principle of Cooperation* (St. Louis, MO: Catholic Health Association, 2005); Catholic Health Association (CHA), *Resources about the Principle of Cooperation* (St. Louis, MO: Catholic Health Association, 2013); The National Catholic Bioethics Center, *Walk as Children of Light: The Challenge of Cooperation in a Pluralistic Society*, ed. Edward Furton and Louise Mitchell (Boston, MA: The National Catholic Bioethics Center, 2003); *Cooperation, Complicity and Conscience*, ed. Helen Watt (London, England: The Linacre Centre, 2009); United States Conference of Catholic Bishops (USCCB), *Ethical and Religious Directives for Catholic Health Care Services*, 5th Ed. (Washington, D.C.: USCCB Publishing, 2009).

[3] CDF, "Some Principles"; USCCB, *Ethical and Religious Directives*, 15.

[4] CDF, "Some Principles," 3.

[5] CHA, "Resources," 45-46; Ron Hamel and Michael Panicola, "Cooperating with Philanthropic Organizations," *Health Progress* 89, no. 2 (2008): 50-51.

[6] Ron Hamel, "Cooperation: A Principle that Reflects Reality," *Health Progress* 93, no. 5 (2012): 80-81.

[7] Barry Johnson, *Polarity Management: Identifying and Managing Unsolvable Problems* (Amherst, MA: HRD Press, Inc., 1996): 81-82.

[8] Steven Squires, "Interpreting Material Cooperation as a Function of Moral Development to Guide Ministry Formation," copyrighted dissertation, Duquesne University (2012).

[9] Pope Francis, *Evangelii Gaudium (The Joy of the Gospel)* (Washington, D.C.: USCCB, 2013), 50-52, 66, 92-94, 108-124.

Unity Across Diversity: Catholic Identity and Physician Practices in Catholic Health Care

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Introduction

This essay emerged from theological reflections begun during a recent experience as a mission leader within a Catholic health system. Our local health system acquired a multi-specialty physician clinic in six locations across three counties in Arkansas. Among the varied business challenges that come with merging or integrating any new organization into an existing business model, e.g., human resources, financial accounting, software compatibility, etc., came the uniquely theological question of mission integration. On a specific day the business transaction was complete and these clinics became nominally Catholic. Accordingly, a plan was developed and put in place that included orientation and education, development of policies and procedures, purchasing art and sacred decorations to depict our Catholic heritage, and the discontinuation of ethically forbidden procedures such as surgical sterilization. Still, even as these efforts were underway, it was troubling that some fundamental conceptual questions were not being addressed, namely "What does it mean for a physician practice to be Christian/Catholic?"

Some might argue these questions have already been answered and that there exists a consensus in general terms within the Catholic health ministry around what constitutes "Catholic identity." Evidence for this would be found in statements such as the "Shared Statement of Identity for the Catholic Health Ministry" (Catholic Health Association 2008), the *Ethical and Religious Directives for Catholic Health Care Services* (United States Conference of Catholic Bishops 2009) and "Caritas in Communion: A Summary" (Catholic Health Association, 2013). In this view physicians, like any other employee, would need to conform to the existing standards of identity.

This approach seems less than adequate. First, while accord may exist within Catholic health care regarding questions of identity, this agreement is principally related to hospitals rather than physician practices. Even regarding hospitals, there is considerably less consensus on specific activities or outcomes around each category that comprise these shared statements. For example, community benefit practices and commitments to spiritual care of patients in Catholic hospitals vary widely among Catholic health systems. This ambiguity is even more evident in regards to integrated physician practices in a Catholic health system, e.g., should physician clinics provide pastoral care? Second, physicians do not view themselves as employees like any other. They

are highly educated, wealthy, and members of a powerful profession. Although physicians as individuals and as a profession have embraced the corporate practice of medicine, they are typically uneasy to abandon the locus of control over their practices to corporate structures (Starr 1982). Thus this diversity must be addressed in another manner.

Anyone familiar with the landscape of modern American health care is aware that the relationship between physicians and health systems has been changing. Hospitals are on a "buying spree" purchasing physician practices and employing physicians. The motivations for these purchases are multi-faceted from both the hospital and physician side. Not surprisingly, religious affiliation or congruity around ethical and theological worldviews is seldom articulated as a reason for physicians seeking partnership or employment with any particular hospital or health system. Given that Catholic hospitals and health systems are engaging in efforts to acquire physician practices or employ physicians in competition with their for-profit competitors serving in the same communities, it seems prudent to pause and reflect theologically on what it means for these physician practices to be Catholic.

These relatively new developments present both challenges and opportunities for religious orders and sponsoring entities of Catholic health systems. From the Cenobitic monasteries of the late Patristic period down through the middle of the twentieth century, religious orders cared for the sick and operated hospitals principally with the labor and leadership of the members of the order. These communities of women and men shared a common tradition and commitment to a Christian vision of health care interpreted through the particular charism of their founders and handed down through the formation of new members of the order. There was a certainty that an institution would be faithful to its roots because they operated in a sense as a "family business" (Grant and Vandeburg 1998). As the numbers of vowed religious declined, the day to day work of teaching, nursing, etc. transitioned to lay persons while the members of the sponsoring community took on a leadership role for "mission fulfillment, quality, critical components of operation…and culture as well" (Grant and Vandeburg 1998). This trend continued with the development of "mission" roles to oversee theological identity, set expectations for employees and develop leadership training and formation for those in administration and governance. In this model in the twentieth century into current times, physicians would collaborate with hospital leadership as members of the medical staff but, with a few exceptions, the medical staff was organized as an independent entity devoted to upholding professional standards around the practice of medicine within the hospital. Although physicians would be expected to adhere to the *Ethical and Religious Directives for Catholic Health Care Services*, this was characteristically understood as avoiding prohibited procedures in the area of reproductive ethics.

Certainly new partnerships can be an opportunity for Catholic health care to further its mission and influence the healing professions, but they can also pose serious challenges to Catholic health care "when partnerships are formed with those who do not share Catholic moral principles"(United

States Conference of Catholic Bishops 2009, 30). In the interest of expediency around "closing the deal" Catholic health systems might align with physician practices that do not share commitments vital to a faithful practice of medicine.

Religious Commitments and the Practice of Medicine

The reality that few physicians are motivated to integrate or seek employment with a Catholic provider primarily based on its faith commitments should not be under emphasized. Although some Catholic health systems pre-screen physicians for "values alignment" prior to employment (Crawford 2011), the majority seek alignment after the deal is completed. In this author's experience with such negotiations, conflicts that might arise between the culture of the clinic and the culture of the Catholic institution are frequently minimized. These phenomena should not be surprising. As ethicist H. Tristram Engelhardt has observed: "In a liberal cosmopolitan culture, sectarian religious commitments go against the grain" (Englehardt, 2001, 154). Thus, there are strong cultural factors that contribute to minimizing the particular religious commitments of a Catholic institution. Physicians who had previously been independent or just coming out of training might rightly be concerned with how religious commitments might interfere with their practice of medicine or their ability to earn a competitive salary. Of course, up-front minimization of the particular norms of a Catholic institution can lead to problems. Engelhardt puts the question succinctly: "How can a corporate ethos be established, if a large proportion of the staff and employees are not even nominally Roman Catholic? On the other hand, if the staff and employees are not enculturated into a Christian ethos, the institution will be a Christian health care institution in name only, or perhaps at best in terms of a few prohibitions, which will appear as external constraints over against the actual life of the institution" (Englehardt 2001, 152). This brings us to the crux of the issue: if physicians and clinics are not going to explicitly confess the same Christian identity of their parent in what way are they Christian?

A thorough examination of the impact of Christianity upon the practice of medicine is beyond the scope of this brief essay but in my studies I have found no scriptural or traditional mandate that physicians practicing within a Catholic physician practice must practice the science of medicine any differently than their secular counterparts save for a few prohibitions which are central to the culture of life. Through the centuries, faithful Christians have utilized the science of medicine (rudimentary as it may have been in earlier times) to relieve suffering. Thus, we acknowledge that although the church continued to utilize physicians in providing care down through the centuries, the "relation between medicine, a secular enterprise, and spiritual healing is at best unclear" (Love 2008, 235). Although "sharing in the healing ministry of Jesus" is a common element in mission statements of Catholic health systems, specifics around this remain vague especially in regards to the practice of medicine (O'Rourke 2001).

Three Possibilities for the Catholic Physician Practice

One possibility is the concept of a "Christian" physician. Christian or Catholic physicians are typically defined through their personal virtues, i.e., their concern and faithfulness to their patients, their care for the poor and their continued attentiveness to prohibitions, e.g., abortions, sterilizations, etc. Pellegrino and Thomasma when describing a Christian physician portray her as "an amalgam of the ethical commitments to the sick by Hippocratic physicians, the divine revelations of Jewish and Christian Scripture, the tradition of healing as an apostolate for all Christians and a coterminous commitment to scientific competence" (Pellegrino and Thomasma 1996, 48). In this view to be a Christian physician is similar to being a Christian carpenter, plumber, baker etc. The skills of one's craft are essentially the same, but how one practices the craft is informed by the distinct nature of the Christian community.

Certainly Catholic health care should welcome such Christian physicians, but simultaneously acknowledge that we live in a diverse world with a plurality of religious and moral beliefs both among physicians and patients. From a practical standpoint, when a typical physician practice integrates into a Catholic health system, there will be a diversity of gender, age, religious affiliations and belief systems among the physicians. This diversity poses a challenge and opportunity. Integrating only Christian physicians would severely impede the possibility of an institutional response to the needs of the sick.

Therefore a second possible response to the challenge is what I would call the "formed physician," i.e., the development of physician formation programs similar to those devised for lay leaders in governance and administration to transmit core teachings regarding the tenets of Catholic health care, encourage individual spiritual growth and delineate and inculcate the behaviors required for those who would serve within the ministry (Yanofchick 2011). This approach seems to have a great deal of merit and indeed has been a dominant force in mission integration programs in hospitals for the past several years. In these approaches, the founding stories of the healing ministry of Jesus are retold and re-imagined in ways that bring new energy and insight to the ministry. The gaps between the current reality and the visions of the founders serve as a catalyst for action and allow new members of the ministry to see their place in the ongoing narrative of the organization (Arbuckle 2013). In regards to physician formation, there are preliminary reports of success throughout the ministry, where physicians have deepened their own understanding of the healing profession and better connected with the healing ministry of Jesus and the charism of the health system's founders (Doyle, 2014). These formation approaches value diversity, but do expect new members to embrace and adopt the identity of the parent organization and accept the founding stories as a motivation for action.

The experience of the Catholic health ministry with physician integration is still in its infancy and so it is probably premature to judge formation programs, but this author is not yet convinced that existing formation programs can be easily replicated in the clinic

due to the strong culture differences between the culture of a physician clinic and that of a hospital or health system. As noted previously, physicians do not view themselves as employees like any other. In many health systems, including my home health system, the physician population reflects greater diversity than the mostly homogenous central Arkansas population. Our employed physician group reflects great diversity in age, gender, country of origin, religion, education, language, etc. With the growth in the divide between hospital-based physicians and clinic-based physicians, many of our employed physicians seldom interact with hospital staff or leadership and have little formal connection to the broader health system ministry. As hospital admissions decline and physician practices become a more identifiable part of the Catholic health ministry, it seems imperative that we clarify how these entities will truly be Catholic in a culture of greater diversity and plurality. I would like to pose for discussion an approach I will call (following communitarian philosopher Charles Taylor) "unity across diversity" which is anchored in an understanding of Catholic identity as rooted in the practice of care for the sick.

The work of Alisdair MacIntyre has provided a convincing argument that we can never achieve widespread consensus on matters of morality, including medical morality in our modern world. All that remains of past consensus are "fragments" of moral language that are no longer anchored in a coherent moral tradition (MacIntyre 1981). Some view these phenomena with extreme pessimism and call on Christian practitioners to set themselves apart from the wider cultural medical establishment. Engelhardt, for example, views the current state of Christian bioethics as in disarray in attempting to placate a secular culture. He sees this as directly traceable to efforts in the 13th century to translate the theological norms of the church into a moral language comprehensible to anyone in the natural law tradition. He views these efforts at using the natural law as ultimately fruitless:

> As our intractable secular moral pluralism demonstrates, a common sense of morality, or even a common sense of the secularly morally reasonable, does not exist for the secular culture beyond its rejection of a fully transcendent God Who determines the nature of the good, the right, and the virtuous (including the content of bioethics). (Engelhardt 2011, 67).

Engelhardt sees the current hostility of secular culture to religion as returning the church to its pre-Constantine status as an embattled minority. He views this as an opportunity for the church to reclaim a more robust confessional theocentric view of morality, medicine and health care as anchored in the truth of the triune God.

Unlike Engelhardt, we look not to conflict but to areas of agreement as a possible clue to building working relationships. There is a growing scientific literature on a biological basis for some types of moral behavior. Thus the near universal accord against killing of innocents, torture and incest may have a neurobiological source. In this view, much of moral discourse is simply rational

interpretation of "unconscious moral intuitions and behaviors" (Gazzaniga 2008).

Within bioethics there is also a strain that claims most ethical reasoning is *post hoc.* For example, one of the "founding myths" of bioethics is the nature of discourse that led to the drafting of the Belmont Report, created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Using an inductive approach, the commissioners came to widespread agreement around particular cases. It was when they attempted to justify why they agreed that they ran into obstacles:

> The one thing individual commissioners could not agree on was why they agreed. Instead of securely established universal principles…giving the intellectual grounding for particular judgments about specific kinds of cases, it was the other way around. The *locus of* certitude in the commissioners' discussions…lay in a shared perception of what was specifically at stake in particular kinds of human situations (Jonsen and Toulmin 1988, 16-19).

In an international consensus, Charles Taylor has observed that widespread agreement can be achieved on the existence of human rights (as in the Universal Declaration on Human Rights) as long as we set aside the theoretical discussion of the foundation of those rights (C. Taylor 1996).

For Catholics this consensus is not surprising. Like Engelhardt, we look to the natural law tradition, but not as the source of our troubles but as a sign that a solution is possible. The natural law tradition has many strains and facets but in a simple sense it teaches that there is order and purpose in the world and that by examining this order and purpose we can determine which choices and activities lead to human flourishing and which impede it. It further argues that these actions can be discovered through the use of practical reason by reflecting upon the nature of humans. For the Christian, this order is discovered because nature reflects the design of the creator. A scriptural basis is found in Paul's Letter to the Romans:

> Indeed, when Gentiles, who do not have the law, do by nature things required by the law, they are a law for themselves, even though they do not have the law. [15] They show that the requirements of the law are written on their hearts, their consciences also bearing witness, and their thoughts sometimes accusing them and at other times even defending them (Romans 2:14-15).

The philosophical roots of the natural law are found in the teleology of Aristotelian ethics and further developed by St. Augustine and St. Ambrose and reach their zenith in the thought of St. Thomas Aquinas. Aquinas came to demarcate a three-tiered set of human goods including life itself, education of offspring, life in society, friendship, marriage, etc. Humans have natural inclination to seek these goods (Aquinas *Summa Theologica* I-II, 94, 2-6). Our point here however is not to defend or justify natural law reasoning nor to translate the claims of Christian faith into

neutral concepts, but instead to point the tradition as justification for a common morality or moral intuitions that can be fostered and nurtured even with persons whose avowed belief systems may be significantly different from our Christian/Catholic worldview.

This is not to encourage a naïve hope that the existence of moral intuitions or a common morality will lead to a moral nation or world. Indeed there is ample evidence for pessimism. Pluralism is not an excuse for relativism or "a kind of Will Rogers pluralism: one where theologians have never met a position they didn't like." (Tracy 1981) Instead we can see the need for a communitarian ethic built on service. The early church's response to poverty and suffering was rooted in the concept of *imago Dei* and this concept, operative in Judaic thought, developed and was transformed by the activity of agape love in the early Church. As time went on the concept of *philanthropia,* which heretofore had not been characterized by private charity or caring for the indigent, was transformed by the early church. This is again possible with the active support of Catholic health care.

Thus against Engelhardt's call to retreat to some pre-Constantine ecclesiology we turn hopefully to a theology for a physician practice built upon practices anchored in a common morality. While not rejecting the primacy of faith, we are more optimistic than Engelhardt regarding the future of Christian health care, arguing that moral pluralism is not an excuse for isolationism. Taking seriously the charge of the Second Vatican Council in the Pastoral Constitution of Church in the Modern World (*Gaudium et Spes*) we acknowledge the interdependence of all persons and the needs for institutions and groups to work together for the benefit of humanity. The church must be in the world, at the service of persons and in dialogue with the world (Hehir 2008, 21). This is the church as faithful individuals, but also the church collective, the institutional church. As Bryan Hehir argues in a discussion of the Catholic health ministry, the Catholic Church is "institutional by instinct and by nature. We often think of the institution as a force that hinders, burdens, or creates obstacles," but he goes on to describe how the complexity of our world demands institutional responses as well as committed personal lives (Hehir 2008, 18).

Our society and our institutions are growing in diversity. Within these institutional lives we find the diversity already described. Communitarian Charles Taylor has argued that human diversity is part of how we are made in the image of the Triune God (C. Taylor 1999). Truly acknowledging this diversity and recognizing it as a part of God's plan is therefore fully "Catholic" and transforms the Gospel mandate to "go and make disciples of all nations (Mathew 28:18) from a unity-through-identity understanding to a unity-across-difference understanding (C. Taylor 1999). Thus, we do not have to make physicians (or any co-workers for that matter) into "Christian" physicians or close approximations to the same through formation programs in order to be faithful to our Christian identity. We do have to ensure that our actions as Christian health care are always faithful to a Gospel rooted in *agape* love. As Michael Himes notes in describing the centrality of service in the Christian faith, "We cannot experience God unless we love

our brothers and sisters and we cannot love our brothers and sisters without experiencing God" (Himes 1995, 55). This is an optimistic note which we would like to build upon.

To "share in the healing ministry of Jesus" must be understood more broadly as practices imitative and illustrative of gospel care and compassion as lived by Jesus Christ and understood by the early church in the term *agape* love. The Epistle of James continues to be instructive:

> What good is it, my brothers, if someone says he has faith but does not have works? Can that faith save him? If a brother or sister has nothing to wear and has no food for the day, and one of you says to them, "Go in peace, keep warm, and eat well," but you do not give them the necessities of the body, what good is it? So also faith of itself, if it does not have works, is dead. Indeed someone might say, "You have faith and I have works." Demonstrate your faith to me without works, and I will demonstrate my faith to you from my works (James 2:14-18).

The Epistle articulates an essential truth in moral epistemology: we do not believe certain things about God, the world, our neighbors, derive universal moral principles and then live according to those principles. Instead we form our beliefs, abstractions, principles from the language and practices that form our lives. Imitating God's mercy, forgiving enemies, giving freely to others, praying etc., can have profound implications on relationships and social practices (Cahill, "The Bible and Christian Moral Principles" 1996, 8).

In our developing relationships with physicians we must engage in dialogue around the practices that can unite us across our ideological differences. Without doubt, there will be practices that the Catholic health system will demand of any physician who wishes to become a part of the ministry including the defense of innocent life, compassion and a willingness to serve the poor. Apart from these essentials there will be a need for dialogue. Certainly, the church does not come empty handed, but neither does it come with all the answers. In faith we believe that in serving the sick and the poor we encounter Christ and this encounter cannot help but be transformative. We remain optimistic that we can come to agreement on what we should do without agreement on why we should do it. We must remain committed to this openness because of the nature of the problems we face and the mandate we have received to care for our neighbors in distress compels us to be open to the Spirit in new ways.

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Ella Revisited

Last November, several mainstream media outlets reported the results of a 2011 study that appeared in the journal *Contraception* that claimed that Plan B (levonorgestrel--LGN) is not effective as emergency contraception for women with a body mass index >25 kg/m.[1] In its place, the authors recommended Ella (ulipristal acetate--UPA) or an intrauterine device. In the wake of this news, CHA received several queries about the use of UPA in Catholic hospitals. These queries prompted an examination of the more recent scientific literature on the mechanism of action of ulipristal acetate. A previous examination looked at the literature from 2010 and 2011.[2] The present review looked at the literature from 2011 until 2014.

There appear to be only two pieces of original research.[3] Using mice, the first study investigated the potential of UPA in blocking ovulation after the onset of the LH (luteinizing hormone) surge which, if it did occur, would explain why UPA is more effective than LGN. LGN, "if administered at least 2 days prior to the luteinizing hormone (LH) surge. … is able to cause either a delay or an inhibition of the LH surge, thereby preventing ovulation in women. However, LNG is unable to prevent ovulation if administered when the LH level has already started to rise."[4] In the present study, the researchers used human chorionic gonadotropin (hCG) which mimics luteinizing hormone.

What the researchers found is that "a single dose (30 mg) of UPA administered immediately before ovulation delays or inhibits ovulation in comparison to placebo-treated cycles. When administered before the onset of the LH surge, UPA, like LNG, delayed the LH peak and ovulation in all cycles. However, when administered after the LH level begins to rise but before it reaches the peak, LNG is ineffective as an ovulation blocker. However, UPA is an effective inhibitor of ovulation within this time period. In humans, the time interval from the rise of LH to its peak level is 30 to 36 hours. It appears that UPA needs to be administered during this time window in order to be maximally effective as an ovulation blocker. Once the LH reaches its peak, the UPA's effect in blocking ovulation declines sharply."[5]

This study did not set out to examine whether UPA might also affect the endometrium. However, the authors do say that while it is clear why UPA has the antiovulatory effect that it does, "we also need to consider the possibility that UPA has the potential to act at other sites including the endometrium."[6]

The second study, quite different in approach, essentially confirms the findings of the first and also does not address possible effects on the endometrium.

Several review articles appeared during the time span in question that address the mechanism of action of UPA.[7] All

essentially confirm the above. Three of the reviews speak to possible effects of UPA on the endometrium.[8] All three say the same thing: "The effect of UPA on the endometrium has also been demonstrated to be dose-dependent. Treatment with 10-100 mg UPA resulted in inhibition of down-regulation of progesterone receptors (PRs), reduced endometrial thickness and delayed histological maturation with the highest doses, while the effect of lower doses equivalent to the 30 mg used for EC were similar to that of placebo."[9] All three refer to one particular study in support of this conclusion.[10] The consensus at this time seems to be that UPA at a dose of 30 mg which is what is administered for EC does not adversely affect the endometrium.

However, there is also an alternative reading of the literature upon which this conclusion rests.[11] Five physicians from the Department of Woman's and Children's Health at the University of Padua, Padova, Italy, take exception with the analysis of the mechanism of action of UPA found in four studies in the primary literature.[12] Upon these studies, "the most authoritative drug agencies and scientific societies report that UPA works by either inhibiting or delaying ovulation."[13] The authors disagree. Here is their reasoning:

> The effects of UPA were reported to be highly dependent on the levels of LH at the time of administration: before the onset of the LH surge, the ability of UPA to delay ovulation was 100%. After the onset but prior to the LH peak, it fell to 78.6%, whereas at the peak and after, it dropped to 8.3%.
>
> Moreover, in the results section, when reporting the interval from UPA intake to follicular rupture, the authors stated and detailed verbatim that "*when UPA was given at the time of the LH peak, the time elapsed to rupture was similar to placebo* …."
>
> This indicates that when either placebo or UPA was administered 1 to 2 days before ovulation, their effects on ovulation were null, which appears to be the opposite of the conclusions of the article. Any attempt to suggest that, even when taken on the day of the LH peak, UPA can still delay ovulation for 24 to 48 hours appears unacceptable. At that time, in fact, both the placebo and the UPA are ineffective and ovulation occurs when it was scheduled to occur, approximately two days after the intake of the tablets. …
>
> This evidence suggests that the effectiveness of UPA relies on other mechanisms, particularly on its endometrial effects.[14]

The authors then go on to describe endometrial effects (essentially the same as those mentioned above) as reported in the three articles they examined.[15] They conclude:

> In our opinion, all the endometrial effects described in these 3 articles are able to interfere with the process of implantation. …
>
> The UPA might also function by delaying ovulation, but this effect has only been consistently proven in the mid-follicular phase before the beginning of the fertile period when EC plays no role. Once the fertile period has started, UPA is able to delay ovulation only before LH increase. Thereafter, this effect is no longer consistent, whereas it is lost in the preovulatory days.
>
> The efficacy of UPA, reported to prevent more than 80% of expected pregnancies, is thus likely to be due to the described endometrial effects that make the tissue unsuitable for embryo implantation.[16]

If these authors are correct in their analysis of the primary literature on the mechanism of action of UPA, then the use of UPA in Catholic hospitals is highly questionable from a moral perspective. If, however, the consensus is correct, then there would seem to be sufficient moral certitude at this time to make use of UPA in Catholic hospitals. In either case, additional study of the mechanism of action of UPA is desirable, especially at the dose that is used for emergency contraception.

RH

Editor's Note: As we were finalizing production of this issue of HCEUSA, we learned that the AP reported on July 24 that the European Medicines Agency announced, after a review of the evidence sparked by the French manufacturer of UPA's declaration that levonorgestrel as an emergency contraceptive didn't work in women weighing more than 80 kilograms (176 pounds), that the drug levonorgestrel is suitable as an emergency contraceptive for heavier women. "The EMA said it had assessed all the available evidence and announced the data 'are too limited and not robust enough to conclude with certainty' that the pill's efficacy is reduced in heavier women. It said the results of these studies should be included in the product information but that current warnings on Norlevo's packaging should be deleted."

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[1] Anna Glasier, Sharon Cameron, Diana Blithe et al. "Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel." *Contraception* 84 (2011): 363-367. Interestingly, five of the co-authors of this article are employees of HRA Pharma that produces ulipristal acetate or Ella.

[2] See Ron Hamel, "Ella (Ulipristal Acetate): Taking another Look." *Health Care Ethics USA* 20, no. 3 (Summer 2012) :17-20.

[3] Shanmugasundaram Nallasamy, Jaeyeon Kim, Regine Sitruk-Ware, Milan Bagchi, Indrani Bagchi. "Ulipristal Blocks Ovulation by Inhibiting Progesterone Receptor-Dependent Pathways Intrinsic to the Ovary." *Reproductive Sciences* 20, no. 4 (2012): 371-81; Vivian Brache, Leila Cochon, Maeva Deniaud, Horacio B. Croxatto. "Ulipristal acetate prevents ovulation more effectively

than levonorgestrel: analysis of pooled data from three randomized trials of emergency contraception regimens." *Contraception* 88 (2013): 611-18.

[4] Nallasamy, 371.

[5] Ibid., 378-79.

[6] Ibid., 379.

[7] Narendra Nath Sarkar. "The state-of the-art of emergency contraception with the cutting edge drug." *German Medical Science* 9 (2011) accessed at www.ncbi.nlm.nih.gov/pmc/articles/PMC3141844/; Shilpa Jadav and Dinesh Parmar. "Ulipristal acetate, a progesterone receptor modulator for emergency contraception." *Journal of Pharmacology & Pharmacotherapeutics* 3, no 2 (April-June 2012):109-111; Kristina Gemzell-Danielson, Cecelia Berger, P.G.I. Lalitkumar. "Emergency Contraception—mechanisms of action." *Contraception* 87 (2013): 300-08; Kristina Gemzell-Danielson, Thomas Rabe and Linan Cheng. "Emergency Contraception." *Gynecological Endocrinology* 29 (2013): 1-14; P.G.L. Lalitkumar, Cecilia Berger, Kristina Gemzell-Danielson. "Emergency Contraception." *Best Practice & Research Clinical Endocrinology & Metabolism* 27 (2013): 91-101.

[8] Gemzell-Danielson, "Emergency Contraception," p. 6; Gemzell-Danielson, "Emergency contraception—mechanisms of action," p. 304; Lalitkumar, op. cit., p.93.

[9] Lalitkumar, p. 93.

[10] P. Stratton, D. Levens, B. Hartog, et al. "Endometrial effects of a single early dose of the selective progesterone receptor modulator CDB-2914." *Fertility and Sterility* 93 (2010): 2035-41.

[11] Bruno Mozzanega, E. Cosmi, G. B. Nardelli. "Ulipristal Acetate: Critical Review about Endometrial and Ovulatory Effects in Emergency Contraception." *Reproductive Sciences* 21, no. 6 (2014): 678-85. See also, Bruno Mozzanega, S. Gizzo, S. Di Gangi, E. Cosmi, G. B. Nardelli. "Ulipristal acetate in emergency contraception: mechanism of action." *Trends in Pharmacological Sciences* 24, no. 4 (April 2013): 195-96.

[12] The four articles are: V. Brache, V., L. Cochon, C. Jesam, et al. "Immediate preovulatory administration of 30 mg ulipristal acetate significantly delays follicular rupture." *Human Reproduction* 25, no.9 (2010):2256-63; P. Stratton, B. Hartog, N. Hajizadeh, et al. "A single midfollicular dose of CDB-2914, a new antiprogestin, inhibits folliculogenesis and endometrial differentiation in normally cycling women." *Human Reproduction* 15, no. 5 (2000): 1092-99; Stratton et al., op. cit. (2010); M.D.Passaro, J. Piquion, N. Mullen, et al. "Luteal phase dose response relationships of the antiprogestin CDB-2914 in normally cycling women." *Human Reproduction* 18, no. 9 (2003): 1820-27.

[13] Mozzanega, p. 680.

[14] Ibid., 681.

[15] Ibid.

[16] Ibid., 682.

Of Note

Cancer Centers' Ads Rely on Emotion, Lack Information, Study Shows

A new study posted on the Annals of Internal Medicine website analyzed 409 unique local and national cancer treatment ads. The researchers found that the ads studied used emotional appeals, messages of hope and patient testimonials more often than descriptions of actual care, mentions of potential risks or references to costs and coverage. The study authors concluded, "clinical advertisements that use emotional appeal uncoupled with information about indicators, benefits, risks, or alternatives may lead patients to pursue care that is either unnecessary or unsupported by scientific evidence." In an accompanying editorial, Dr. Gregory Abel, a Harvard Medical School assistant professor, warned that forcing centers to give more information in ads could lead to false claims and general misinformation. Andis Robeznieks, *Modern Healthcare*, May 28, 2014

Medicare Patients Frequently Get Double Chest Scans, Critic Charges

According to data published last December by the Centers for Medicare and Medicaid Services (CMS), more than 1.4 million outpatients received double chest CT scans. A hospital can bill Medicare twice if patients are scanned once with iodine and then again without. The report found that in 500 hospitals 10% of their outpatient CT chest-scans are double scans. Data from the CMS is updated annually and available for free download at Medicare's Hospital Compare website, https://data.medicare.gov/. Joe Carlson Modern Healthcare, April 1, 2014

Light-Sensitive Retina Created with Human Stem Cells

In a study published in the journal Nature Communications, researchers were able to turn human induced pluripotent stem cells (iPS) into retinal progenitor cells that form light-sensitive retinal tissue. M. Valeria Canto-Soler, lead author and an assistant professor at Johns Hopkins, stated that the lab-grown photoreceptors respond to light in the same manner as retinal rods. This process allows the lab to create hundreds of mini-retinas at a time from a patient with retinal disease. Although the system has potential, Canto-Soler cautions this is only the beginning, "Is our lab retina capable of producing a visual signal that the brain can interpret into an image? Probably not, but this is a good start." Marie Ellis, http://www.medicalnewstoday.com/articles/278025.php

Scientists Hail Synthetic Chromosome Advance

Dr. Jed Boeke at the Langone Medical Centre at New York University led an international team that created the first synthetic chromosome for yeast. In the

field of synthetic biology, the creation of a yeast chromosome is considered "a massive deal" because yeast cells contain a nucleus and share 2,000 genes with humans. The new chromosome, known as SynIII, was successfully integrated into a yeast cell which then reproduced and passed a viability test. In creating the new chromosome, the researchers removed repeated sections in the original DNA causing the yeast to gain new functions. Critics argue that the scientists are "playing God" by creating new forms of life. David Shukman,
BBC News Science & Environment
March 27, 2014,
http://www.bbc.com/news/science-environment-26768445

For Elderly Hospital Patients, CPR Often Has Poor Outcome

A study published in the journal Age and Aging examined survival rates of patients undergoing in-hospital CPR. Dr. Dionne Frijns, a geriatric medicine researcher at Diakonessenhuis hospital in Utrecht, and her team reviewed 29 studies that involved 417,190 patients over the age of 70. Their findings indicated that 40 percent of patients had successful CPR but more than half of those patients eventually died in the hospital. In light of these findings, the study authors stated "there could be certain elderly patients for whom CPR is worthwhile intervention," but "future research should focus on pre-arrest factors" to help determine the individual's CPR benefits. Dr. William Elenbach, a specialist in pulmonary and critical care at the University of Wisconsin, is concerned about possible functional deficits in patients who are successfully resuscitated, "we just don't have a good base of studies to help us estimate what the likelikhood of a new deficit of neurologic disability is." Shereen Jegtvig, *Reuters Health*, May 9, 2014

Climate Change Will Overwhelm U.S. Health Care System, Report Warns

A Risky Business Project, a bipartisan group that includes investor and philanthropist Thomas Steyer, former Treasury Secretary Hank Paulson and former New York Mayor Michael Bloomberg, released a report warning about the effects of climate change on business and public health. The report found that in 2009 and 2010 the annual incident rate of heat stroke in the emergency room was 1.3 visits per 100,000 people. The incidence of heat related health problems is predicted to rise as the annual number of days where the temperature will reach 95° will be as many as 50 by 2050 and by the end of the century could reach 96. According to the report, climate change will have an especially negative effect on those living with chronic health conditions. Dr. Alfred Sommer, professor of Epidemiology, Ophthalmology and International Health at the Bloomberg School of Public Health, states that the current health system could not handle the influx of patients. "We are going to get this perfect storm of reduced capacity to deal with sudden large bad events, and we are going to get sudden, bad events at a much greater likelihood and frequency than we

do now." Steven Ross Johnson, *Modern Healthcare*, June 25, 2014

Air Pollution Kills 7 Million People Every Year, World Health Organization Report Finds

According to a World Health Organization report, air pollution is the cause of about one in eight deaths making it the biggest environmental health risk. The report estimates that in 2012 there were 4.3 million deaths caused by indoor air pollution and 3.7 million deaths caused by outdoor air pollution. Due to the fact that many people exposed to indoor air pollution are also exposed to outdoor air pollution, the overlap of those effected brings the total estimate around 7 million to 8 million deaths. This new figure is more than double previous estimates. Almost 90 percent of deaths caused by outdoor air pollution occur in developing countries and women had higher levels of exposure than men. Experts are calling for more research to determine which types of air pollution are more deadly in order to control it more effectively. Maria Cheng, March 25, 2014, http://www.huffingtonpost.com/2014/03/25/air-pollution-deaths_n_5027320.html

Students from the Center for Health Law Studies at the Saint Louis University School of Law contributed the following items to this column. Amy N. Sanders, assistant director, Center for Health Law Studies, supervised the contributions of health law students Michael K. Morton (J.D. anticipated 2014) and Courtney E. Thiele (J.D. anticipated 2014).

Judge Overturns Massachusetts Ban on Controversial Painkiller

U.S. District Judge Rya W. Zobel overturned an executive order by Massachusetts Governor Deval Patrick that had banned the controversial painkiller Zohydro ER in the state. Zobel based her decision on the premise that Patrick's executive order preempted federal law by banning a drug that had already been approved by the Food and Drug Administration (FDA). Zobel ruled that Governor Patrick's order "would undermine the FDA's ability to make drugs available to promote and protect the public health." Zohydro ER is a very strong painkiller in the opioid family, the first drug of its kind to contain a pure dose of hydrocodone, which is why the drug has received so much criticism, especially from Patrick. The governor criticized the ruling as one that puts the interests of wealthy drug companies over the interests of public health and safety. Patrick stated, "Addiction is a serious enough problem already in Massachusetts without having to deal with another addictive narcotic painkiller sold in a form that isn't tamper proof." On the other hand, supporters of the drug welcome Zohydro ER's strength, claiming that it allows chronic pain sufferers to take the drug for longer periods of time, limiting the effects of liver damage. Interestingly, the FDA approved the drug last year over the objection of an independent advisory panel, which recommended rejection of Zohydro ER by an 11 to 2 vote. State attorneys general across the nation have also expressed their disapproval of

Zohydro ER, claiming that easy access will hinder their efforts in trying to end the country's prescription-drug abuse crisis. Brady Dennis, *Washington Post*, April 15, 2014, http://www.washingtonpost.com/national/health-science/massachusetts-cannot-ban-fda-approved-painkiller-judge-rules/2014/04/15/91436946-c4db-11e3-b574-f8748871856a_story.html.

$1.2 Billion Judgment Reversed by Arkansas Court

The Supreme Court of Arkansas recently overturned a $1.2 billion judgment against drug manufacturer Johnson & Johnson, ruling that the state improperly sued the company under a state law that applies to health care facilities, not pharmaceutical companies. The underlying lawsuit was brought against Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, for the alleged fraudulent marketing of Risperdal, an antipsychotic drug. Specifically, the state had argued that the companies had not properly communicated the risks associated with Risperdal, and also had marketed the drug for various off-label uses. Risperdal and similar antipsychotic drugs have been linked to increased risk of strokes and death in elderly patients, along with seizures, weight gain and diabetes. The state sued under law that allows for such legal action if fraudulent drug practices would have an adverse effect on a state program, such as Medicaid. The lawsuit accused the companies of deceptive trade practices and Medicaid fraud in marketing of Risperdal, and sought repayment for millions to Arkansas's Medicaid program for unnecessary prescriptions. In their successful appeal, the companies' attorney argued that there was no fraud or improper reimbursements for Medicaid patients who were prescribed the drug. Chuck Bartels, Associated Press/U.S. News, March 20, 2014, http://www.usnews.com/news/business/articles/2014/03/20/arkansas-court-tosses-12b-judgment-against-j-j.

Replacement for Pap Test Recommended by Feds

A federal advisory committee for the Food and Drug Administration (F.D.A.) recommended by a 13-0 vote that a DNA test should be approved for use as a primary screening tool for cervical cancer. The committee touts the DNA test as a possible replacement to the Pap test, a tool that has been the primary screening device for cervical cancer over the past 60 years. While Pap testing involves examining a cervical sample under a microscope, searching for abnormalities, the DNA test, labeled the Roche test, detects the DNA of human papillomavirus, or HPV, which causes almost all cases of cervical cancer. If the committee vote is adopted by the F.D.A., the DNA test would be allowed to be used as the primary screening tool for cervical cancer in women 25 years of age and older. Proponents of the new Roche test call the DNA screening more objective, rather than the analysis of a Pap test, which may vary doctor to doctor or laboratory to laboratory. Skeptics of the new test are weary of such a quick change

in clinical testing if one were to occur. Andrew Pollack, *New York Times*, March 12, 2014, http://www.nytimes.com/2014/03/13/health/an-fda-panel-recommends-a-possible-replacement-for-the-pap-test.html.

RESOURCES

Editor's Note: The following articles appeared in the literature over the past few months and might be of interest to readers of HCEUSA. Their inclusion here does not indicate endorsement by CHA.

Barina, Rachelle. "Risk-Reducing Salpingectomy and Ovarian Cancer." *The National Catholic Bioethics Quarterly* 14, no. 1 (Spring 2014): 67-79.

Brown, Gratan. "Clarifying the Concept of Medical Futility." *The National Catholic Bioethics Quarterly* 14, no. 1 (Spring 2014): 39-45.

Dresser, Rebecca. "Toward a Humane Death with Dementia." *Hastings Center Report* 44, no. 3 (May-June 2014):38-40.

Fiester, Autumn. "The 'Quality Attestation' Process and the Risk of the False Positive." *Hastings Center Report* 44, no. 3 (May-June 2014):19-22.

Howland, John and Peter Gummere. "Challenging Common Practice in Advanced Dementia Care: A Fresh Look at Assisted Nutrition and Hydration." *The National Catholic Bioethics Quarterly* 14, no. 1 (Spring 2014): 53-63.

Menzel, Paul T. and M. Colette Chandler-Cramer. "Advance Directives, Dementia, and Withholding Food and Water by Mouth." *Hastings Center Report* 44, no. 3 (May-June 2014):23-37.

Of Interest

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The master's program in health care ethics at Saint Joseph's University is designed to prepare individuals for the complex and growing field of biomedical ethics. The program fosters a critical analysis of bioethical topics through the interplay between moral theory and medical practice. For more information, visit www.sju.edu/grad/hce or contact the Program Director, Mark Aita, S.J., M.D. at 610-660-3427 or email maita@sju.edu.

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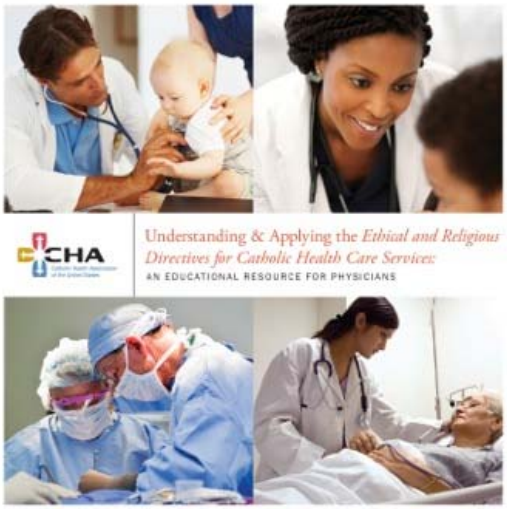

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