

Health Care Ethics USA

A quarterly resource for the Catholic health ministry

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In This Issue

Ethical Currents

PAGE 1

Of Note

PAGE 41

Feature Articles

Embedding Clinical Ethics Upstream:
What Non-Ethicists Need to Know

PAGE 3

John Paul Slosar, Ph.D.

Response to Bayley and Gremmels on
Transgender Ethics

PAGE 12

E. Christian Brugger, Ph.D.

Is the Soul Sexed? Anthropology, Transgenderism,
and Disorders of Sex Development

PAGE 18

Elliott Louis Bedford, Ph.D. & Jason T. Eberl, Ph.D.

From the Field

A Bitter Pill: Prescription Drug Costs and
Direct-to-Consumer Advertising

PAGE 34

Rev. Charles Bouchard, OP, S.T.D.

Editor's Comments

HEALTH CARE ETHICS USA (Summer 2016)

We are pleased to present, first of all, an article by John Paul Slosar of Ascension Health on what “non-ethicists” need to know about ethics. His thoughtful remarks are geared to “spread the joy” of ethical thinking to more than just ethics professionals. As our beloved former colleague Jack Glaser used to say, “There are no ethics-free zones.”

Even though some of us do have specialized education and background in this area, the publicity surrounding ethical issues in health care and the vastly expanded involvement of patients and families in ethical decision making demands that we think of ways to create greater awareness and broader participation.

We then return to our discussion of issues in transgender health care. Previous articles by Carol Bayley, Kevin FitzGerald and Beckett Gremmels made it clear that ethical issues surrounding transgender persons and their health care are complex and multifaceted. There are psychological aspects, medical aspects (including hormone therapy, cosmetic and urogenital surgery, and ordinary care for non-TG related conditions¹) and legal issues. Transgenderism also involves genetics and embryology because we do not yet fully understand the origin of this condition. Legal issues

have become more pressing since the final HHS non-discrimination regulations took effect on July 18.² These rules require that we examine both our clinical and human resources policies.

Finally and perhaps most importantly for us, there are philosophical and theological questions. These pertain directly to transgender persons, but they also raise fundamental questions about what it means to be human. Elliott Bedford and Jason Eberl present an exploration of philosophy, personhood and the soul. E. Christian Brugger of St. John Vianney Seminary in Denver and the Culture of Life Foundation in Washington, D.C., responds to Bayley and Gremmels.

Our purpose in publishing these articles is to deepen our understanding of what is in many ways a new issue. Transgender persons have always been among us, of course, but our awareness of them and of the many issues that impact them are new. Our assumption is that there is no definitive magisterial church teaching on transgenderism or gender dysphoria. Our conviction is that our Catholic tradition has the resources to address these questions and we hope this ongoing dialogue will help to do that.

Despite questions that remain, we can affirm the following:

- 1) We provide health care services to anyone who comes to us, regardless of gender, sex, race or any other personal quality.
- 2) We guarantee equitable access to services for all persons.
- 3) We are committed to respect the dignity of each person and to “meet them where they are” – socially, psychologically, pastorally and economically.
- 4) We will remain faithful to our mission and values and will maintain our corporate integrity as we deal with these issues in a pluralistic society.

The final article is a discussion of ethical issues around direct-to-consumer advertising of prescription medication. This began as a pet peeve for me. I am part of a generation that still gets much of its news in traditional ways, e.g., newspapers and TV. I still watch the evening news on network television and have been annoyed by the increasing number of ads for prescription drugs. That annoyance eventually led ethical curiosity. My article is the result of my investigation. It is an overview of some of the ethical questions that surround direct-to-consumer advertising. I believe this trend deserves much closer attention.

¹ See the World Professional Association for Transgender Health “Standards of Care” available in E. Coleman et al., “Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming

People,” Version 7 (*International Journal of Transgenderism*, 2011, v. 13:165-232) and also on the WPATH web page (www.wpath.org).

²A summary of the new HHS regulations are available in the June issue of the United States Conference of Catholic Bishops’ *Law Briefs* (June 2016), pp. 6-18, “HHS Issues Final Regulations on Nondiscrimination in Federally-Funded Health Programs and Activities.” The Kaiser Family Foundation has an online summary of the regulations at <http://kff.org/disparities-policy/issue-brief/summary-of-hhss-final-rule-on-nondiscrimination-in-health-programs-and-activities/>

Embedding Clinical Ethics Upstream: What Non-Ethicists Need to Know

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Introduction

Historically, clinical ethics consultation has been a reactive endeavor epitomized, if not regaled, by tales of the “Friday afternoon consult” regarding the procedure scheduled for first thing Monday morning or, worse, the 2:00 a.m. phone call regarding the mother-to-be in distress. In the best case scenario, we are able to provide quick reassurance that the “medically appropriate” course of action is also “ethically appropriate.” Alternatively and less desirably, we may be called upon to mediate an entrenched and irresolvable conflict between a patient’s family and care-team after a 60 day stay in the ICU. We all already know that most of the time such cases end unfortunately with the patient’s inevitable expiration (despite all our technology), and the ethics service appearing somewhat impotent. The latter of course is not

a result of our failure to respond to the call or any lack of competency in doing so, but rather the fact that the call itself came far too late for anyone who doesn’t carry a magic wand to be successful in addressing it.

In an attempt to improve the services we provide to those we serve and to those clinicians who serve on behalf of our ministry, the Ethics Advisory Leadership Council of Ascension is in the process of developing a model of “Proactive Ethics Integration” that improves institutional capacity to influence clinical decision-making in anticipation of potential ethical concerns.¹ To do this, we are moving away from the traditional paradigm of an expert-centered deployment model of ethics and towards one that embeds systemic approaches and standardized resources for identifying and addressing clinical ethical issues upstream in

existing and emerging clinical and organizational processes as close to the point of service as possible, whether that is at the bedside, in the Ambulatory Surgery Center, the Skilled Nursing Facility or Physician Offices. The first step of developing such a model is equipping a system-wide team of “embedded ethics resources,” comprised of unit and service-line based personnel, with some level of ethics competency in order to be able to proactively identify ethical issues in the course of their daily activities and address at least some of them before they become too entrenched or complex, or to triage those issues that require an additional level of expertise sooner than commonly happens today. The fundamental question in this endeavor, then, is what do busy clinicians with no formal ethics training need to know about ethics, if we are to be successful in proactively integrating ethics upstream in person-centered care.

First Things First

The first thing the non-ethicist needs to know is what ethics even is and how it ought to be conceptualized. While this may seem too obvious, I am not simply referring to the standard Google or even academic definition of ethics, but an understanding of ethics that fits both within a Proactive Ethics Integration

framework and within the medical profession’s understanding of its own fundamental commitments. The task is complicated by the fact that most clinicians bring with them some preconceived notion of ethics, usually from their secular clinical training. Subsequently, clinical ethics is often seen as conflict mediation, especially in the absence of any robust normative framework to situate objective moral truth above and beyond patient autonomy understood simply as “what the patient wants.” Within this framework, the need for clinical ethics services is sometimes subconsciously seen as a signal that the physician has somehow failed to fulfill their obligations in the correct way. Worse yet, clinical ethics services within the Catholic health ministry is sometimes naively viewed as who you call when you do not want to run afoul of *The Ethical and Religious Directives for Catholic Health Care Services* (ERDs) and/or “get in trouble with the bishop.” Regardless, an inappropriate or inadequate understanding of ethics and the clinical ethics service will either lack any incentive or actually disincentivize clinicians to call upon ethics services as a resource.

Within Ascension, we have begun exploring an alternative conception of ethics as a key enabler of the Quadruple aim, i.e., improved outcomes, reduced costs and the best possible patient and

provider experience, with a special emphasis on “Healing without Harm.” While “Healing without Harm” primarily refers to the elimination of medical errors and avoidable mortality,² it provides a good context for grounding the concept of ethics in the foundational norm of the medical profession itself: first, do no harm. From the perspective of the person understood holistically and integrally and adequately, i.e., as an integrated body-spirit unity, this makes sense insofar as ethics can be understood as a service aimed at reducing, minimizing or avoiding spiritual, emotional, psychological and social/relational harm as well as sometimes actual physical harm that results both from illness and the care process itself. As with medical errors, the cause of spiritual, emotional, psychological or social/relational harm is generally not the ill will of individuals, but more often systems and process failures and the inattentiveness of human beings trying to do too much. Thus, just as with initiatives aimed at “Healing without Harm,” ethics within the context of Proactive Ethics Integration ought to be thought of as the systematic implementation of normalized processes intended to identify early opportunities to prevent and reduce spiritual, emotional, psychological and social/relational harm before it occurs as a result of well-intentioned efforts. While it would in fact be

more accurate and perhaps complete to say that ethics supports care-providers and families in addressing complex questions that arise from the sacredness of every person, their unique beliefs, values and life-story within the context of their specific health needs, the concept of healing the whole person without spiritual, emotional and relational harm seems to be one which clinicians can readily grasp and easily buy into.

Ethical Dimensions of Person-Centered Care

Early identification of the ethical dimensions of person-centered care before the point at which one might recognize the presence of a more traditionally understood “ethics case” is vital for Proactive Ethics Integration or any effort to move ethics upstream. Ideally, there would be a set of easily recognizable ethics indicators that would signal the presence of an ethics issue before it becomes entrenched, irresolvable or even just obviously apparent. While some ethicists, such as Carol Pavlish and Katherine Brown-Saltzman, have been doing some excellent work in this area, the focus within the secular literature is generally on ethics understood as a conflict between decision-makers or when one is faced with an unpleasant choice between undesirable outcomes.³ In the clinical context especially, ethics tends to be

seen as relevant only when one is faced with a difficult dilemma. Within the Catholic understanding of ethics as the promotion of human dignity and human flourishing, however, the ethical dimensions of care go far beyond the traditional notion of a dilemma. Thus, once the educational foundation regarding an appropriately robust understanding of ethics has been laid, the next thing clinicians will need to know is what constitutes the ethical dimensions of person-centered care, even in those cases in which a conflict or dilemma is not present or may never even emerge.

Of course, difficult decisions between two bad choices or conflict among decision-makers are ethical dimensions of care that will always need to be addressed. The point is simply that the relevance of ethics is not and ought not be limited to instances of dilemmas classically understood as being trapped between a rock and hard place. Yet it is sometimes the case that we fail to see the ethical dimensions of cases in which two or more *positive* values may be competing for our moral attention. While this scenario is generally not seen as an ethical issue because its resolution properly falls within the realm of patient autonomy (i.e., because the values that are at stake are all positive, it's simply a matter of patient choice), it is easy to make the mistaken assumption that the patient adequately

understands what values are at play or the relationship of the proposed course of treatment to those values. While the role of ethics in this scenario is less about avoiding "harm," it certainly falls within the scope of supporting persons in making complex decisions and healing the person holistically understood.

In other instances, the care-providers may overlook the ethical trade-offs at play when it is clear what ought to be done or what value ought to be pursued from one isolated perspective, say for example the clinical perspective. When we focus too much on only one dimension of the human person, such as patho-physiologic processes, we often fail to recognize the effect the illness is having and our care will have regarding different values of equal or even greater significance when understood from a spiritual, emotional, psychological or relational perspective. The tendency to overlook the relevance of these values can sometimes lead to a false sense of certainty regarding the appropriate goals of care. To be clear, I am not faulting anyone, especially physicians, for approaching medical practice from a clinical outcomes perspective. After all, I wouldn't want my own physician to think any other way. The point is merely that there are often ethical issues at play long before a classic end-of-life or beginning-of-life dilemma rears its head.

What then are the ethical dimensions of person-centered care that clinicians need to be able to recognize and respond to sooner rather than later? While the details and specifics will obviously vary from case to case, we can say in very general terms based on the reflections above that the short list would include, at a minimum: 1) any salient moral values or personal goals of the patient or patient's family that are impacted by the illness, injury or plan of care; 2) any goods or harms that may be in or come into conflict with one another; 3) any lack of clarity regarding the goals of treatment, which may or may not lead to conflict regarding those goals; and 4) any ambiguity about the application of organizational policy and the ERDs.

Regarding numbers 1 and 2, I am not suggesting that these are the clinicians' responsibility to address, but only that Ethics services can help enhance care that is truly person-centered when these ethical dimensions are recognized. Care-providers can and should be aware of how these personal values and goals of the patient may influence their decision-making regarding their treatment options. Regarding number 3, this clarity can often be achieved short of involving the ethics service, and having clarity around these goals will allow

the care team to communicate more effectively with patients and their families as the medical situation changes and the feasibility of those goals of treatment may be impacted. The fourth ethical dimension identified above is important for two interrelated reasons. First, the ERDs articulate the objective normative framework that guides the organizations particular vision of what constitutes holistic, person-centered care. Thus, the role of the ethics service is not merely to mediate conflict or convince the relevant decision-makers to go along with what has been deemed the clinically best decision, but to help all parties—patients, surrogates and care-providers alike—understand both the limits and possibilities of all treatment options in light of the inherent dignity of every human life. Second, the earlier that ERD or policy related issues are identified, the sooner and more programmatically they can be addressed. The more this happens, the more these considerations will be seen as facilitating rather than impeding efficient, person-centered care consistent with the standards of sound medical practice.

Awareness of these ethical dimensions of person-centered care is especially important with regard to the ability of clinicians not only to recognize further upstream when ethics services can be of support, but also to be able to

identify the central question that should be addressed. Adequate isolation and articulation of the specific ethical dimensions of care will help minimize the number of consult requests that are really just questions that no one else wants to deal with and/or don't fall neatly within the scope of accountability of any one specific job description. This also helps reduce the frequency of the ethics service being called upon to give a second opinion because someone didn't like the first answer they received or opine on a matter beyond their expertise, such as a legal or medical judgement. Moreover, it is difficult to come up with the right answer in response to the wrong question. In some cases, just the very act of reframing and articulating the right central question in light of the ethical dimensions of an issue brings clarity as to the resolution itself. Finally, the ability to identify and articulate the right central question will help ensure the type of ethics support that is most appropriate, efficient and effective for addressing a particular issue.

Not All Ethics Issues Are the Same

A key insight in the design of our model of Proactive Ethics Integration was the realization that not all ethics issues are the same and not all issues require the same level of expertise. In a more traditional model, influenced by the

medical model of physician specialization, ethics is often seen as the sole purview of one specific expert. If you have an ethics issues, you ask the ethicist; just like if you have a heart problem, you ask the cardiologist. Proactive Ethics Integration, however, requires that clinicians whose primary expertise lies somewhere besides ethics be willing and able to act as embedded ethics resources right on the unit or within the service line (in the outpatient setting). This function entails that clinicians be able to answer certain types of more basic ethics questions as part of—rather than in addition to—the performance of their primary clinical responsibilities. Within this model, they also need to know when to triage the more complex issues.

Through reflection on the different types of consultations we have been tracking for a couple of years, the Ethics Advisory Leadership Community of Ascension came to the realization that there are essentially four basic types of ethics consultations entailing varying degrees of complexity: 1. General Advisements, 2. Policy Clarifications, 3. Patient Care Consultations, and 4. Retrospective Case Analysis. General Advisement consists of offering an opinion or clarification for informational purposes only, i.e., the response will not formally be used as the basis for altering

a patient's plan of care. An example of this would be when someone hears of a planned procedure or something that has just occurred and is curious as to how it fits with our Catholic identity. For example, a nurse might say, "I heard they are planning to induce the woman with Preterm Premature Rupture of Membranes and Chorio-amnionitis in room 425, I thought we didn't do that in a Catholic hospital?" The response won't be used to affirm or alter the particular plan of care, but it will help to clarify that and how the planned procedure is consistent with the ERDs for those who might not already understand this. With the right training, there is no reason that the OB Nurse Manager can't be equipped to answer this question, which occurs frequently enough on that unit that it really should not require taking the time to reach out to the ethics committee or ethics service.

As the name suggests, Policy Clarification consists of identifying, applying or clarifying relevant institutional policies and/or the ERDs for the purpose of influencing a patient's plan of care. A common example of this is the question of Do-Not-Resuscitate (DNR) orders in the perioperative setting. There should be at least one person in the surgery center who is aware that the institution has such a policy (assuming it does), who is aware of what it says and who is

able to address the concerns of a surgeon who is hesitant to perform the surgery unless the DNR order is suspended.

Patient Care Consultations are what we traditionally associate with the work of the ethics service and entail a process of gathering facts, identifying norms, and engaging various stakeholders in order to arrive at a recommendation intended to influence a patient's plan of care, and therefore will likely need to be documented in the patient's medical record. While a proactive approach to integrating ethics in the clinical life of the organization will not eliminate the need for Patient Care Consultations, it should increase the capacity of Ethics Committee Members to lead these consultations without the assistance of a trained ethicist. And, as previously noted, there will always be instances of conflict between decision-makers and true ethical dilemmas in the delivery of health care. It remains important, therefore, for clinicians to know how to access the ethics committee or ethics consultation service when the complexity of a case requires it.

Retrospective Case Analysis consists of post-discharge review of a specific case for the explicit purpose of improving existing care processes. Within a framework of Proactive

Ethics Integration, a complex Patient Care Consult is not the end of the work of the ethics service but just the beginning of the work to integrate an institutionalized response to address or even prevent repeat occurrences of the issue further upstream in the care process. Being familiar with this taxonomy of ethics consultation will enable clinicians to know who they can turn to for support in the most efficient and effective manner, once they have recognized that there are ethical dimensions within the delivery of person-centered care that might warrant some sort of ethics support whether from an embedded resource on the unit (or service line), the ethics committee or a formally trained ethicist.

Conclusion

I have taken a long and winding route to arrive at a list of the key things clinicians need to know about ethics. I chose this route because what clinicians need to know about ethics depends on the role we want clinicians to have in addressing ethical issues. If we are content with the traditional model of ethics services, then it should be enough for clinicians to know how to recognize the presence of an ethical dilemma or conflict among decision-makers and who to call in response. Of course, in a Catholic institution, they should also be aware

that the ERDs exist, that they are contractually obligated to abide by them when practicing within the institution and, probably, they should know a little something about any specific directives that are directly relevant to their area of medical practice.

If, however, we want clinicians to take a more proactive role in integrating ethics in upstream clinical processes, then clinicians also need to have additional understanding of the value that ethics can contribute to the patient experience by helping to prevent spiritual, emotional and relational harm and keeping the person truly at the center of person-centered care. Along with this more robust concept of Ethics, clinicians also need to understand the different dimensions of an issue that makes it an ethics issue as opposed to a legal, risk, or spiritual care issue, for example. Finally, familiarity with the different levels of complexity entailed by different types of ethics issues will enable clinicians to access the targeted type of ethics support they need in the most efficient and effective manner possible, which just might also lead to improvements in the provider experience as well.

¹ Our model of Proactive Ethics Integration is similar to the model of Next Generation Ethics Committees, but with difference stemming from a greater emphasis on

embedded ethics services rather than on the committee itself. See, for example, Murphy, Kevin. “A ‘Next Generation’ Ethics Committee.” *Health Progress* 87 (March-April 2006): 26-30.

² Pryor, David, Ann Hendrich, Robert J. Henkel, et al. “The Quality Journey At Ascension Health: How We’ve Prevented at Least 1,500 Avoidable Deaths a Year—And Aim to do Even Better.” *Health Affairs*. (April 2011): 604-611.

³ See, for example, Pavlish, Carol L., Joan Henriksen Hellyer, Katherine Brown-Saltzman, et al. “Screening Situations for Risk of Ethical Conflicts: A Pilot Study.” *American Journal of Critical Care*. (May 2015): 248-257.

Response to Bayley and Gremmels on Transgender Ethics

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I offer here a reply to two articles from the Winter 2016 edition of *Health Care Ethics USA*, the first by Carol Bayley and the second by Becket Gremmels, on whether it is morally legitimate for Catholic healthcare institutions to perform “sex reassignment surgery” (SRS) on persons experiencing gender dysphoria (GD).

Bayley argues for two related conclusions: first, that Catholic healthcare institutions, indeed everyone, should relate to GD individuals according to their “gender of choice”; and second, that Catholic institutions should perform SRS on at least some patients who ask for it. I will argue that both her conclusions should be rejected.

Bayley grounds her first conclusion in what might be called the principle of respect. She says that although Sacred Scripture and Catholic teaching do not directly address the problem of GD, there

is much in these sources to help us think about them. For example, she says they teach respect for individuals, admonish us to welcome strangers, praise diversity in nature, etc. This alone, she says, is “sufficient” to make us understand “the necessity of treating transpersons with respect.”

Bayley’s use of Scripture to ground her conclusion is simplistic. Revelation teaches that God creates human beings as males or females. In cases where maleness or femaleness is unambiguously expressed in one’s anatomy and genetic make-up (i.e., where one either has female primary sex characteristics and two copies of the X chromosome at the 23rd pair, or male sex characteristic and one X and one Y chromosome) the Christian presumption is that the *whole person*, body and psyche, is that sex. Until recently “gender” was a synonym for “sex”. Bayley says the two are distinguishable. Gender, she says, refers

to “the social and behavioral aspects” of sex. But whether we follow her understanding or the traditional one, it would be inconsistent with Divine Revelation to affirm that at the level of human identity—not mere feelings, but ontological nature—a man can ever be “trapped” in a woman’s body or vice versa. Unless we concede an unsound body-self dualism, one’s sex—i.e., one’s embodied reality as male or female—is defining of one’s whole self. This then can be used to interpret the problem of gender dysphoria. If it is true that the whole self exists as either male or female, any deep and intractable mental distress at being one’s given sex is expressive of a disharmony between one’s affect and reality. The assumption, therefore, is that the experience is an expression of a disorder, which deserves understanding, treatment and prevention, not reinforcement.

Moreover, since we do not have persuasive evidence that GD is not a psychological disorder; and we have good evidence to the contrary; hospitals and practitioners that treat GD as if it is a healthy expression of personal identity are willing if wrong to treat serious pathology as a healthy condition. This is irresponsible, grossly so. It’s like treating an intra-cranial growth that hasn’t been ruled out as a brain tumor as if it clearly is *not* a brain tumor. Any responsible clinician (and healthcare institution) would rule

out reasonable doubt that some condition is not seriously harmful before treating it as healthy or benign, and for heaven’s sake, before prescribing treatments that strengthen it. And at present we certainly cannot rule out that GD is an extreme expression of body-identity hatred, more severe even than anorexia nervosa or body dysmorphic disorder.

Bayley’s second conclusion is that Catholic hospitals may legitimately carry out all four phases of SRS on GD individuals, including so-called “top” and “bottom” surgeries. Appealing to “double effect” reasoning, she argues that the “end” of this kind of surgical intervention is good, namely, relief from serious discomfort and distress; that the means is also good or at least neutral, namely, a surgical procedure; and that the tolerated but unintentional harm, i.e., reproductive sterilization, is reasonable to accept in light of the sought-after benefits.

In itself, the relief of suffering is a good thing. Bayley’s assumption, however, that patients who undergo SRS will experience such relief seems unjustified. She herself concedes that “there is a great deal we do not understand” about the relationship between gender and biological sex (p. 2), and both she and Gremmels note that there is no reliable empirical evidence that SRS ameliorates the sufferings of persons with GD.

In fact, there is good evidence that the long-term effects are deleterious. Dr. Paul McHugh, former psychiatrist in chief at Johns Hopkins Hospital, who had significant clinical experience with individuals who underwent SRS, wrote in the *Wall Street Journal* in 2014:

Most of the surgically treated [i.e., SRS] patients described themselves as “satisfied” by the results, but their subsequent psycho-social adjustments were no better than those who didn’t have the surgery. And so at Hopkins we stopped doing sex-reassignment surgery, since producing a “satisfied” but still troubled patient seemed an inadequate reason for surgically amputating normal organs.¹

McHugh refers to a 30-year longitudinal study in Sweden published in 2011 that followed 324 SRS patients. The study revealed that “beginning about 10 years after having the surgery, the transgendered began to experience increasing mental difficulties. Most shockingly, their suicide mortality rose almost 20-fold above the comparable non-transgender population.”

¹ Available at <http://www.wsj.com/articles/paul-mchugh-transgender-surgery-isnt-the-solution-1402615120>

Finally, Bayley refers only to a single harm caused by SRS when she assesses proportionate reason, namely, “contraceptive sterilization”. This seems terribly superficial. What about the anatomical harm caused by mutilating healthy sex organs? What about the harm to relationships that persons undergoing SRS risk, especially harms to their children? What about the danger of scandal, and the risk of reinforcing another individual in delusional ideas about his self-identity, and contributing to the cultural advance of what Pope Francis calls “gender ideology”, etc.?

Becket Gremmels, drawing on the teaching of Pope Pius XII, appeals to the “principle of totality” to argue (1) that SRS is not intrinsically evil; and (2) that because its efficacy is not well assured, the surgery is not presently justifiable. He argues that according to Pius’ account of totality, an organ need not be pathological to justify its amputation or destruction. It needs simply to pose a serious threat to the “being of the whole” (p. 8). For persons suffering from GD, Gremmels says, the presence and normal functioning of healthy body parts, “contributes to and exacerbates” the dysphoric condition (p. 7); therefore, “SRS could be justified from a Catholic moral perspective” if it was chosen to benefit the patient’s health, and the sterilization it causes was merely tolerated as an “indirect, unintended, but foreseen side-effect”. But, he says, we would also

need reasonable certitude of the efficacy of the procedure in treating the condition. Gremmels argues that presently “evidence on the effectiveness of SRS” is lacking. Therefore, although SRS is not intrinsically evil, it is presently not morally acceptable.

Gremmels’ first conclusion cannot be accepted as argued. He nowhere acknowledges that changing our biological sex is impossible. Our sex is written into every one of our 60 trillion or so cells. SRS is therefore a pretender’s game. Whether Gremmels thinks that one’s sex really can be “reassigned” is unclear. What is clear is he believes that reassignment surgery could be morally acceptable. But to counsel, perform or accept for oneself any surgery believing or asserting that what’s happening is that a person is changing (“reassigning”) his biological sex would always be contrary to the truth and therefore always impermissible. In other words, to participate in SRS following the assumptions about sex and gender held today by secular culture *would be intrinsically evil*.

Could one ever participate in so-called “top” or “bottom” surgery in a way that is fully consistently with truth? It seems to me possible. A doctor and other caregivers would have to be convinced on reasonable grounds that a particular patient could never find psychological peace aside

from the surgery, that is, it would have to be a last resort. And they would have to be truthful that what’s going on is not a sex change or a gender change, but a gravely disfiguring surgical procedure aimed at realizing whatever psychic stability is possible in this life. Whether such a disabled person truly could be benefited by these surgeries, is still uncertain.

But even if the surgeries were performed in a way that was consistent with the truth, other conditions, not mentioned by Gremmels, would need to be met before Catholic hospitals could rightly perform them. Without trying to be exhaustive, I mention a few.

1. The problem of scandal

People seeing Catholic hospitals or practitioners participating in these types of surgeries might be led to approve of the false assumptions about sex and gender underlying many attempts at gender manipulation today, or to engage wrongfully or encourage others to engage wrongfully in actions flowing from the assumptions. Leaders of Catholic healthcare institutions therefore would have a grave responsibility to ensure that any participation in these surgeries *do not cause scandal*.

2. Contributing to culturally flawed attitudes about sex and gender

If a Catholic hospital or practitioner were to recommend or carry out “top” and “bottom” surgeries, even under the narrow conditions set forth above, it would likely give the impression that they agree with the flawed assumptions about sex and gender that stand behind much of today’s “gender ideology”. Therefore, those involved in the decision or procedures would have an obligation to do what they could to ensure that their participation would *not* contribute to culturally flawed attitudes about these important areas.

3. The problem of non-marital and homosexual behavior

Bayley dismisses the question of the relevance of Catholic teaching on homosexuality for the problems of GD and SRS (p. 2). But this fails to consider the situation of a GD individual who has begun to “identify” with the opposite sex and begins to act out sexually with individuals of the sex with which he or she has ceased to “identify”. Apparently, this is not uncommon. Catholic hospitals and

clinicians would have a duty to soberly assess whether any kind of participation in “top” or “bottom” surgeries would wrongfully contribute to GD individuals experiencing heightened temptations to engage in non-marital sexual behavior.

4. Bad effects on the cooperator

If Catholic hospitals begin to perform these surgeries, it may result in hospital leaders and employees growing indifferent to the serious issues at stake in the larger “transgender” question. Leaders of Catholic institutions would therefore have a duty to ensure that their cooperation over time does not lead to the coarsening of themselves or their employees in relation to moral truths pertaining to sex and gender.

5. Unfairness towards vulnerable dependents and relationships

A very grave issue that neither author considers is unfairness towards those for whom persons with gender confusion have special moral responsibilities. The spouses and especially the children and other immature dependents of those who begin publically to “identify” as the opposite sex, and worse, attempt to alter their bodies to

appear like the opposite sex, can be harmed terribly and unfairly by their loved-one's decisions. This is probably the locus of the gravest evils arising from "gender ideologies". In my opinion, for those with vulnerable dependents and other relations, the cases where undergoing these surgeries would not be unfair and so immoral are extremely rare if not practically non-existent.

6. Christian witness of Catholic hospitals

As apostolates of the Catholic Church, Catholic healthcare institutions have a duty to bear witness to the truths of the Gospel, and against those evils that are especially harmful to people's temporal and eternal welfare. "Gender ideology" is certainly one of those evils. Catholic healthcare institutions have an especially serious obligation to witness to the truth that God 'made them male and female,' and against the popular but erroneous notion that biological sex, "gender identity", and

"sexual orientation" have no intrinsic coherence.

7. The duties of medical practitioners

Neither article addresses the grave duty of medical practitioners to avoid faddism in treatment plans and to act reasonably towards patients, respecting the goods of their bodies and souls, and only recommending harmful procedures when they have good reasons to believe that such procedures offer significant hope of benefit to suffering patients.

Is the Soul Sexed? Anthropology, Transgenderism, and Disorders of Sex Development

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Introduction

The recent articles by Bayley, Gremmels, and FitzGerald touch on a timely issue.¹ While such articles focused on narrow methodological issues, we intend to examine relevant questions about anthropology. To develop this insight, we build upon traditional and recent magisterial teaching, as it is informed by Thomistic philosophy, and juxtapose the conditions known as *transgenderism* with *disorders of sex development*. To conclude, we draw some preliminary implications such discussion has for

properly distinguishing and specifying the moral object of genital surgeries in each context.

Conceptual and Linguistic Precision

Because precision of language is so important in emerging issues, we will begin by addressing some terminological points to help structure the dialogue among Catholic moral theologians and ethicists.

First, it is now common to distinguish conceptually between *sex*, which refers to the biological/anatomical characteristics of being

male or female based on one's chromosomal identity, and *gender*, which refers to the perception of being male or female typically as it relates to socially defined roles usually ascribed to a particular sex.² Such conceptual differentiation does not mean that the two are unrelated or have some intrinsic connectivity, whether practically or theoretically. To assume otherwise is to beg a central question at issue.³ At the same time, even a cursory review of the literature reveals the terms are often used interchangeably, if not equivocally.⁴ Our commentary will strive to maintain a balance which recognizes that distinction does not entail disconnection.

Second, the term “transgender” (TG) refers to “persons whose gender identity, gender expression or behavior does not conform to that typically associated with the sex to which they were assigned at birth.”⁵ Previously this condition was recognized with a clinical diagnosis of “gender identity disorder.” The diagnostic term now favored by the DSM-V, “gender dysphoria,” denotes not only differing gender identification but also consequent significant feelings of distress.⁶ TG is therefore not reducible to gender dysphoria—since not all persons with differing gender identification experience distress about this perception—and one need not experience distress to seek out

hormonal or surgical interventions. It is notable that the linguistic and diagnostic shift emphasizes the assertion that *distress* is the problematic phenomenon, not the self-identified incongruence between sex and gender.⁷

Third, disorders of sex development (DSD) are categorically distinct from transgenderism. Also known as “intersex” conditions, DSD are “defined by congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical.”⁸ Lack of a DSD is, in fact, one of the diagnostic exclusion criteria in a differential diagnosis for gender dysphoria.⁹

In sum, while sex and gender may be conceptually distinct, they are not necessarily practically disconnected. Similarly, TG and DSD are conceptually and clinically distinct, though both touch on the relationship between sex and self. These phenomena each raise important practical questions around the best way to provide a loving, healing, personal response to persons with these conditions in line with the pastoral approach affirmed by Pope Francis.¹⁰ Yet, we can only start to develop answers to these questions when we explore these distinct conditions in light of the anthropological insight found in church teaching.

Basic Christian Anthropology

Implicitly or explicitly, all Christian moral theology is grounded in a theological anthropology that is itself informed by a *philosophical* anthropology. The latter provides a framework for formulating a perspective on questions related to transgenderism that is not uniquely Christian and thereby debatable within the public square. As “a sure norm,” the *Catechism of the Catholic Church* no. 355 outlines four basic components of an authentically Christian anthropology: Human beings occupy “a unique place in creation” as 1) created “in the image of God;” 2) in our nature uniting “the spiritual and material worlds”; 3) created “male and female”; and 4) established by God in “friendship.” These form the bones from which our faith understands human beings and our essential nature. Each of the points, moreover, may be supported to a certain extent through philosophical argument. For instance, the first and final points affirm the philosophical insight that all human beings share equally in a common human nature. This common nature provides the

ground for the moral requirement to recognize and respect *all* human persons, regardless of gender identity, as divinely created for the purpose of attaining loving union with their Creator.

The second and third points establish certain constitutive elements of this received human nature. Rejecting the extremes of reductionist materialism and substance dualism, these points affirm the view set forth by Thomas Aquinas (c. 1225-1274) that human beings exist as composite unities of an immaterial soul informing matter to compose a living, sentient, social, and rational animal;¹¹ and, by virtue of our animal nature, we are essentially *sexed* beings. However, by virtue of our essentially integral nature as a body-soul unity (*corpore et anima unus*), saying that one’s sex is determined by one’s animal nature is not to say that one is male or female only at the *physical* level. For, once God infuses a rational soul into a properly formed human body,¹² the body being the principle of the soul’s *individuation* as well as of its sex, the soul now carries that individuality and sex with it as an “inseparable accident” insofar as it is the *form* of its particular body.¹³ It serves as

the “blueprint” for its body such that one’s resurrected body will be properly *his* or *hers*, including with respect to its sex.¹⁴ As John Grabowski summarizes, “sexual difference is accidental on the level of human nature but essential to actually existing persons.”¹⁵ Therefore, the living material body, which is the human being, is constituted with inherent meaning and this meaningfulness encompasses and is manifested through our biological sex.

Moving beyond philosophy, but not *contrary* to a philosophical understanding of God as one divine substance, Christian systematic theology posits that human beings mirror the divine Trinity. That is, human bodily existence is primarily *personal* and *relational* with respect to God, other persons, and creation.¹⁶ Our personal sexed nature is also inherently *dispositive* towards God’s ongoing creative act through our sexual complementarity. Hence, the *Catechism* no. 2360 states: “sexuality is ordered [*per se*] to the conjugal love of man and woman.” In sum, sex is *per se* an inherent, ineradicable, given, and dispositive feature of actual human beings. Yet, this point does nothing to

rule out a *per accidens* reality that sexed bodies might have developmental disorders or that we may not fully understand an individual person’s sex.

The *Catechism*, as noted above, characterizes human beings as uniting “the spiritual and material worlds.” While there are myriad ways of specifying the relation of “spirit” and “matter” in composing human nature, the church’s magisterium and moral tradition have generally affirmed the Thomistic thesis that human beings are essentially “rational animals” comprising a material body informed by a rational soul (*Catechism* no. 365, citing the Council of Vienne (1312)). While strictly speaking the soul, which is immaterial, is not sexed, each soul is created by God as the vivifying principle of sexed bodies and is thereby individuated and sexed as an inseparable accidental quality of the human being. In short, as the vivifying principle of actually existing human beings, the human soul is properly characterized as sexed.

If the soul is sexed, is it also gendered? Thomistic anthropology provides

reasons to consider the soul as also taking on gender as an inseparable accidental quality that continues to inform a person's psychological orientation after death. According to Aquinas, a human soul persists beyond its body's death by virtue of its immaterial intellectual and volitional powers. These powers are present as *active potentialities* from the moment a rationally ensouled human being comes into existence; their *actualization*, however, develops over time and is informed by the various intellectual and moral inclinations that Aquinas, following Aristotle, terms "virtues" and "vices"—e.g., wisdom, prudence, fortitude, etc.¹⁷ These virtues, once cultivated through habit, as influenced by one's social environment and pattern of free choices—or sometimes directly infused by God—become defining features of one's intellectual and moral *character*; as such, they can only be removed with difficulty,¹⁸ and, upon death, persist as indelible marks of one's soul.¹⁹

Insofar as one's social milieu plays an essential role in shaping his or her character, combined with the fact that

one inherently relates to other persons in terms of his or her gender, it is reasonable to conclude that the indelible stamp of intellectual and moral traits definitive of a person's self-identity also includes their gender-identification. Furthermore, one's soul also retains self-consciousness—i.e., a person's unique *first-person perspective*²⁰—and the intellectual knowledge one had acquired throughout life.²¹ All of these psychological traits, combined with the indelibly "sexed" quality of one's soul, support the thesis that one's soul becomes, and persists beyond death through resurrection, as "gendered." To assert otherwise is to bifurcate the essential integral nature of our body-soul unity, laying the foundation for a problematic body-self dualism, which we will discuss later.

This thesis supports our view that sex and gender are conceptually distinct, yet inherently connected. As Charlotte Witt contends, gender is *uniessential* to one's identity as a "social individual" that is, in her view, ontologically distinct due to its foundation in interpersonal relationships, yet grounded in one's existence as both a person and a human

organism. She contends that, while transgender individuals may alter their identities as social individuals, they would persist as the same persons and organisms.²²

While we reject Witt's ontological separation of one's identity as a social individual, we affirm that one's gender is largely grounded in one's *relational identity* with other persons, though also inherently informed by one's biological make-up since others relate to us largely due to our apparent physical sex. Since, for Aquinas, one's soul is both the ground of one's psychological traits—including self-consciousness, intellectual knowledge, and virtues or vices—and the form of one's physical body, it follows that one's soul is both sexed and gendered.

Comparing Disorders of Sex Development and Transgenderism

These basic Christian anthropological assumptions allow us to contrast the phenomena of DSD and TG. This juxtaposition will provide a framework for offering an ethical analysis of specific interventions.

First, neither DSD nor TG is incongruent with Christian tenets about the origin, moral dignity, and final end of persons with these conditions. All are created children of the one God, share the same irreducible moral status, and are called to eternal life. How these conditions relate to our bodily, sexed life requires further articulation.

We believe that DSD does nothing to challenge or repudiate the essence of the anthropology outlined above.²³ The questions raised by persons with DSD take the embodied nature of human persons very seriously and thus are not inherently adhering to a problematic "body-self dualism."²⁴ The question this situation presents is objective and ontological: it is not a question about how one perceives themselves, but what sex the person actually is, given that the biological data might not offer certitude, especially given the variety of intersex conditions that may lead not only to ambiguity in one's external genitalia but also more subtle variations at the less readily observable hormonal level.²⁵ Thus, DSD does not repudiate a binary of sexual complementarity insofar as the

question at hand is not whether there are more than two sexes or a spectrum of sexual identity; indeed these conditions are only intelligible in light of a male-female sex binary. Rather, they show that *per accidens* there is variation in the degrees and types of biological development within the categories of male and female. Further, the moral message of the Intersex Society of North America (ISNA) and Catholic authors like Erik Lenhart is that surgery ought not be forced upon individuals with these conditions, especially children who are unable to consent for themselves.²⁶

TG differs from DSD, however, by being premised on a discrepancy between the perceiving mind and the existing body—a body-self dualism. Consider how one transgender writer, Anna Magdalena, describes the situation: “for many transsexuals the site of gender embattlement is their **subconscious sex**, which is often confused with **gender identity**. Subconscious sex is a person’s persistent embodied sense of belonging to one sex or another. It is not how one chooses to identify, but how one experiences oneself.”²⁷ Subconscious sex is reportedly

confronted and experienced as a given, not simply an option with which one chooses to identify. Magdalena then associates “subconscious sex” with the disputed concept of “brain sex”—i.e., the biological constitution and disposition of the brain as it has developed under the influence of hormones and other biological factors.²⁸ Hence, a conflict is perceived when subconscious sex is misaligned with genital morphology, which is also confronted as a given. Incongruity between these two perceived “givens” leads to distress and sets the context and impetus for surgery. Thus, gender dysphoria results in a perceived “war” between the brain and the genitals.²⁹ “Genital surgery,” Magdalena writes, “cures ONE problem: the discordance between the brain and the genitals. It does nothing else [e.g., cure psychological comorbidities such as depression], and shouldn’t be expected to do anything else.”³⁰ However, the effectiveness of genital reconfiguration interventions to ameliorate adequately gender dysphoria, and especially associated psychological comorbidities, has long been a source of dispute.³¹

Genital reconfiguration does not necessarily cure either gender dysphoria (distress), transgender identification, or alter the person's "brain sex." Indeed, some transgender proponents affirm that such interventions do nothing to change biological sex: "I am not female nor ever will be. I am a simulation of the female form."³² However, the more fundamental issue is the evident body-self dualism, that the "real" self is not the body as given but merely the "self" as *perceived*. The discordance, then, is primarily *epistemic* in nature. Surgical intervention thus involves manipulating the body to align with one's subjective self-perception. Admittedly, the lived experience of transgender individuals is a critical factor in the exploration of questions regarding gender identity. We must be cautious, however, in not putting total stake in self-perception alone, as subjective experience is not always the best indicator of what is truly the case—e.g., a schizophrenic patient may believe without any doubt whatsoever that they are talking with another person who, in reality, is not present; or, more closely analogous to the present case, someone with body dysmorphic disorder may feel like they

should be an amputee, but most surgeons would not amputate someone's arm solely for that reason.³³

Conclusion: Towards Specifying a Moral Object

Having established elements of a basic philosophical and theological anthropology, it is now possible to offer some reflections on points necessary for moral analysis. The first point is that human moral equality does not necessarily mandate uniform treatment. In fact, equity of care requires that we respond to each case based on its own merits. Conceptually and clinically, DSD and TG are distinct phenomena; the surgical and hormonal interventions that might be licitly used in each case therefore also differ in kind.³⁴ Due to space constraints, and given that "bottom surgeries" would seem to carry greater moral gravity due to entailing the permanent radical alteration of a non-life-threatening healthy procreative organ and its sterilizing effects, we will focus on genital/reproductive organ surgical interventions.

First, DSD surgeries seem to take seriously the composite nature of human beings. For instance, the premise of such surgeries seems to be that, while as animals our anatomy and physiology typically develop toward their teleologic ends (e.g., eating, moving, reproducing), *per accidens*, there is: 1) a degree of variation within the category of what is biologically typical; and 2) a chance the body might develop atypically, i.e. outside of the general spectrum within a given category. Hence, DSD does not comprise an incongruity with one's "authentic" self or imply that one's soul is not properly informing their body, but rather that one's body has developed in a species-atypical way. The immediate end, then, of such surgeries is to correct atypically developed anatomy.

Second, while one might claim that the ultimate end of TG surgeries is body-soul integrity, the immediate end of such surgeries seems to be inescapably premised upon and reinforces a form of body-self dualism. For instance, a Cartesian analysis might claim that TG surgery conforms the body to the soul, positing that the "real" person is the soul.³⁵ This substance dualism, as we

have noted above, is incompatible with a Christian anthropology and so is any justification built upon it.

Conversely, a reductive materialist analysis might claim that the surgery aligns the sex of the genitals with the gender of the brain.³⁶ But this argument presumes that such a duality does, in fact, exist and that the proposed intervention actually ameliorates the duality. Hence, unless there is some yet to be discovered scientific evidence to the contrary, it is doubly incongruent with a Christian anthropology, since the accidental exposure or lack of exposure of the brain to particular hormones does not entail a change in the essential nature of a particular animal or one of their parts (organs). Thus, even if the "brain-sex" hypothesis that exposure of the developing brain to certain hormones is a contributing factor to cross-gender identification is validated, it cannot be said that such exposure causes a change in the essential nature of the person.

Further, to argue that genital reconfiguration helps align or integrate a person as a composite being, one must

deny at least one of the following tenets of Thomistic hylomorphism upon which Christian anthropology has been authoritatively based since the Council of Vienne: 1) that the soul is simple and not comprised of parts (e.g., the part informing the brain is female while that informing the genitals is male), or 2) an organ of a live human being that is typically developed (even those atypically developed) and functional is not properly informed by a human soul. In short, to argue that TG surgery integrates a human person, one must presume that the alleged ontological dis-integrity actually exists. The strong thrust of the Catholic philosophical tradition indicates this is not plausible; the dis-integration lies elsewhere, not on the level of ontology, and at present there is no evidence of a biological dis-integration. To summarize, it is implausible to affirm that the immediate end of these interventions is bodily (i.e., personal) integration. It seems rather to be the reconfiguration of typically developed anatomy.

This conclusion calls for a more refined analysis of the applicability of principles invoked by Bayley and Gremmels in

their reflections on surgical interventions for transgender individuals: *double-effect* and *totality*, respectively. For double-effect is applicable only if an act's immediate end is good or at least morally neutral, and this is precisely what has not heretofore been demonstrated. Further, reconfiguring typically developed and functioning anatomy cannot be construed as either unless, perhaps, the principle of totality is invoked to justify the sacrifice of one part of the body for the sake of the well-being of the whole person. Our analysis calls this latter claim into question, as we have argued that transgender individuals are not experiencing an ontological dis-integration, even if they perceive themselves to be. Consequently, the object of the act of such surgeries could not be described as integrating the person as a body-soul composite.

In sum, our anthropological analysis aims to help theologians and ethicists gain clarity in precisely defining the moral object of genital surgeries, particularly in the context of TG. To aid future analyses, therefore, we propose the term “transgender genital reconfiguration interventions” (TGRI)

as a term that captures both the circumstances and immediate end of such acts—i.e., reconfiguring typically developed anatomy—and avoids some question-begging assumptions. This immediate end is distinct from genital reconstructive interventions in cases of persons with atypical genitalia due to DSD.

¹ See Becket Gremmels, “Sex Reassignment Surgery and the Catholic Moral Tradition: Insight from Pope Pius XII on the Principle of Totality” *Health Care Ethics USA* 24.1 (2016): 6-10; Carol Bayley, “Transgender Persons and Catholic Healthcare” *Ibid.*: 1-5.; Kevin FitzGerald, “Viewing the Transgender Issue from the Catholic and Personalized Health Care Perspectives” *Ibid.* 24.2 (2016): 7-10.

² See Charlotte Witt, *The Metaphysics of Gender* (New York: Oxford University Press, 2011). Note that this dyadic categorization is further complicated by the fact that the biological category of “sex” may be subdivided into one’s chromosomal identity and the phenotypic expression of such, which may be affected by epigenetic factors.

³ See Albert Moraczewski, “Reflections on Chapter 10” in *Sex and Gender: A Theological and Scientific Inquiry*, ed. Mark F. Schwartz, Albert S. Moraczewski, and James A. Monteleone (St. Louis: Pope John Center, 1983), 301. Transgender writer Anna

Magdalena notes their interconnection as well: “*sex* – as opposed to *gender* – refers to biological factors that often exist on a binary. And *gender* – as opposed to *sex* – refers to how we interpret, embody, and personalize those biological factors, as well as all peripheral issues tied to them. The fact remains that we need that second word – gender – simply because humans do in fact interpret, embody, prioritize, and personalize their sex characteristics, and whenever we’re talking about sex, we’re inevitably talking about gender too.” “What is Gender? Or Why the Term is Both Meaningless and Indispensable” <https://catholictrans.wordpress.com/2015/08/16/what-is-gender-or-why-the-term-is-both-meaningless-and-indispensible/> (accessed 5/17/2016).

⁴ This fact is not surprising since etymologically the terms share the same original meaning.

⁵ American Psychological Association, “What does transgender mean?” <http://www.apa.org/topics/lgbt/transgender.aspx> (accessed 6/2/2016). On the linguistic change, see http://www.huffingtonpost.com/2013/06/04/gender-dysphoria-dsm-5_n_3385287.html (accessed 5/17/2016).

⁶ “Gender dysphoria is defined by strong, persistent feelings of identification with the opposite gender and discomfort with one’s own assigned sex that results in significant

distress or impairment. People with gender dysphoria desire to live as members of the opposite sex and often dress and use mannerisms associated with the other gender.”

<https://www.psychologytoday.com/conditions/gender-dysphoria> (accessed 3/7/2016).

⁷ Fitzgibbons et al. offer arguments to affirm the psychopathological status of the cross-identification, not merely the distress.

Richard P. Fitzgibbons, Philip M Sutton, Dale O’Leary, “The Psychopathology of “Sex Reassignment” Surgery: Assessing Its Medical, Psychological, and Ethical Appropriateness” *The National Catholic Bioethics Quarterly* 9.1 (2009): 97-125. In contrast, TG activists

have a clearly stated goal to de-psychopathologize this phenomenon, removing it from the DSM altogether.

<http://www.gendercentre.org.au/resources/act-sheets/transsexualism.htm> (accessed 5/3/2016). See also Alice Dreger, “Why Gender Dysphoria Should No Longer Be Considered a Medical Disorder” *Pacific Standard* [https://psmag.com/why-gender-dysphoria-should-no-longer-be-considered-a-medical-disorder-](https://psmag.com/why-gender-dysphoria-should-no-longer-be-considered-a-medical-disorder-f3f9211a707a#.v9ynp0f57)

[f3f9211a707a#.v9ynp0f57](https://psmag.com/why-gender-dysphoria-should-no-longer-be-considered-a-medical-disorder-f3f9211a707a#.v9ynp0f57) (accessed 6/2/2016). Explaining the linguistic change and diagnostic emphasis, the American Psychiatric Association states, “DSM-5 aims to avoid stigma and ensure clinical care for individuals who see and feel themselves to

be a different gender than their assigned gender. It replaces the diagnostic name ‘gender identity disorder’ with ‘gender dysphoria,’ as well as makes other important clarifications in the criteria. It is important to note that gender nonconformity is not in itself a mental disorder. The critical element of gender dysphoria is the presence of clinically significant distress associated with the condition.”

<http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf> (access 6/2/2016) This linguistic and diagnostic shift is not without its critics. Cf. Lawrence, Anne A. 2014. “Gender Assignment Dysphoria in the DSM-5,” *Archives of Sexual Behavior*. 43 (7): 1263-1266.

⁸ Alice Dreger, “Why ‘Disorders of Sex Development’? (On Language and Life)” <http://alicedreger.com/dsd> (accessed 5/17/2016).

⁹ See Helen Okoye, “Gender Dysphoria DSM-5 302,85 (F64.9)” [http://www.theravive.com/therapedia/Gender-Dysphoria-DSM--5-302.85-\(F64.9\)](http://www.theravive.com/therapedia/Gender-Dysphoria-DSM--5-302.85-(F64.9)) (accessed 5/17/ 2016); Ananya Mandal, “Diagnosis of Gender Dysphoria” <http://www.news-medical.net/health/Diagnosis-of-Gender-Dysphoria.aspx> (accessed 5/17/2016).

¹⁰ See Pope Francis, *Amoris laetitia*, ch. 8. https://w2.vatican.va/content/dam/francesco/pdf/apost_exhortations/documents/papa-francesco_esortazione-

[ap_20160319_amoris-laetitia_en.pdf](#)

(accessed 5/2/2016).

¹¹ See Thomas Aquinas, *Summa theologiae* (*ST*), Ia, q. 76; Jason T. Eberl, “Aquinas on the Nature of Human Beings” *Review of Metaphysics* 58.2 (2004): 333-65.

¹² There is some degree of debate, even among Thomists, of when a developing human body is properly formed for rational ensoulment, with Aquinas himself claiming that ensoulment occurs several weeks post-conception (*ST*, Ia, q. 118, a. 2). The generally, though not universally, held view, especially among Thomists operating within the Catholic tradition, is that rational ensoulment occurs at conception; see Jason T. Eberl, “Thomism and the Beginning of Personhood” in *Defining the Beginning and End of Life: Readings on Personal Identity and Bioethics*, ed. John P. Lizza (Baltimore: Johns Hopkins University Press, 2009), 317-38.

¹³ See Thomas Aquinas, *Quaestio disputata de anima*, a. 12 *ad* 7; John Finley, “The Metaphysics of Gender: A Thomistic Approach” *The Thomist* 79.4 (2016): 585-614; Deborah Savage, “The Nature of Woman in Relation to Man: Genesis 1 and 2 through the Lens of the Metaphysical Anthropology of Aquinas” *Logos* 18.1 (2015): 82.

¹⁴ See Jason T. Eberl, “The Metaphysics of Resurrection: Issues of Identity in Thomas

Aquinas” *Proceedings of the American Catholic Philosophical Association* 74 (2000): 215-30.

¹⁵ John Grabowski, *Sex and Virtue: An Introduction to Sexual Ethics* (Washington, D.C.: The Catholic University of America Press, 2004), 111.

¹⁶ See Alasdair MacIntyre, *Dependent Rational Animals: Why Human Beings Need the Virtues* (Chicago: Open Court, 1999).

¹⁷ See *ST*, Ia-IIae, qq. 49ff.

¹⁸ See *ST*, Ia-IIae, q. 53, a. 1 *ad* 1.

¹⁹ With the exception of the infused theological virtues of faith and hope, which are no longer necessary (*ST*, Ia-IIae, q. 67).

²⁰ See Aquinas, *Summa contra Gentiles*, bk. II, ch. 49; *Scriptum super libros Sententiarum*, bk. II, d. 19, q. 1. a. 1; *In Librum de causis expositio*, prop. 15. For further discussion of the importance of self-consciousness as grounding the soul’s immateriality and the persistent identity of the person it composes, see John Haldane, “(I Am) Thinking” *Ratio* 16.2 (2003): 124-39; Lynne Rudder Baker, “The Difference that Self-Consciousness Makes” in *On Human Persons*, ed. Klaus Petrus (Frankfurt: Ontos Verlag, 2003), 23-39.

²¹ See *ST*, Ia, q. 89, aa. 5-6.

²² See Witt 2011, 88.

²³ Megan Defranza argues that DSD does present a challenge to the binary model of sex in recent Christian anthropology. Historically, Defranza claims, the concept of the “eunuch” has existed and served the

social role of containing those bodies that did not fit easily within the categories of male or female. With the recent developments in medical and surgical science, and an increasingly strongly emphasized binary, DeFranza argues that the socially useful category of the eunuch has disappeared; a development which she argues marginalizes and diminishes sensitivity toward peoples with such conditions. See her *Sex Difference in Christian Theology: Male, Female, and Intersex in the Image of God* (Grand Rapids: Eerdmans, 2015).

²⁴ See Patrick Lee and Robert George, *Body-Self Dualism in Contemporary Ethics and Politics* (Cambridge: Cambridge University Press, 2008).

²⁵ See Claire Ainsworth, “Sex Redefined” *Nature* 518 (19 Feb. 2015): 288-90.

²⁶ See <http://www.isna.org> (accessed 4/30/2016); Erik Lenhart, “People Born with Intersex Conditions: Pastoral and Bioethical Considerations” *The National Catholic Bioethics Quarterly* 15.3 (2015): 453-63. See also Sharon Anderson, “Disorders of Sexual Differentiation: Ethical Considerations Surrounding Early Cosmetic Genital Surgery” *Pediatric Nursing* 41.4 (2015): 176-86.

²⁷

<https://catholictrans.wordpress.com/2015/08/18/what-is-gender-part-4-gender-as-social-grouping/> (accessed 5/18/2016).

²⁸ It is theorized that *in utero* exposure to testosterone masculinizes the brain. Simon van Rysewyk provides a nice summary of this theory: “The brain is thought to develop in the male ‘direction’ through a surge of testosterone on nerve cells; in the female ‘direction’ this surge is absent ... Call this the ‘standard view of gender identity’. The standard view of gender identity offers a plausible explanation of transsexualism. Since sexual differentiation of the brain occurs in the second half of pregnancy, and sexual differentiation of the sexual organs occurs in months 1-2 of pregnancy, transsexuality may occur. The relative masculinization [sic] of the brain at birth may not reflect the relative masculinization of the genitals ... According to the standard view, transsexualism is entirely dependent on, and thereby reduces to, specific neurophysiological changes that occur during intrauterine growth in two interconnected organ types (i.e., brain and genitals)”

<https://simonvanrysewyk.wordpress.com/2013/04/27/mind-brain-identity-theory-brain-sex-theory-of-transsexualism-and-the-dimorphic-brain/> (accessed 6/9/2016). For a critical view of this theory, see Anne Lawrence, “A Critique of the Brain-Sex Theory of Transsexualism (2007)” http://www.annelawrence.com/brain-sex_critique.html (accessed 6/10/2016).

²⁹ See Anna Magdalena, “A Critique of Paul McHugh’s ‘Surgical Sex’”

<https://catholictrans.wordpress.com/2014/02/09/a-critique-of-paul-mchughs-surgical-sex/> (accessed 2/29/2016); Francine Russo, “Is There Something Unique about the Transgender Brain?” *Scientific American* 27.1 (2016)

<http://www.scientificamerican.com/article/is-there-something-unique-about-the-transgender-brain/> (accessed 6/2/2016).

³⁰ Ibid. While the language of transgender activists typically reflects this dualism, it is important to note that this could be construed as a purely materialist argument: the psychological thought (the thinking being) is one gender while the genitals (the material being) are another. However, neither arrangement is consistent with the Thomistic hylomorphic tenets of traditional Christian anthropology as affirmed magisterially by the Council of Vienne.

³¹ For instance, Lawrence cites “a recent article by Dhejne et al. (2011), which reported the results of a long-term follow-up study of 324 Swedish transsexual patients who underwent legal, hormonal, and surgical sex reassignment between 1973 and 2003. Despite their “successful” reassignment, these transsexual persons displayed strikingly higher mortality rates than nontranssexual controls; in particular, they were over 19 times more likely to die from suicide. They were also hospitalized for

psychiatric disorders nearly 3 times more often than controls, and they attempted suicide about 5 times more often” “Gender Assignment Dysphoria in the DSM-5” http://www.annelawrence.com/gender_assignment_dysphoria.html (accessed 6/10/16); citing Dhejne, C., Lichtenstein, P., Boman, M., Johansson, A. L., Långström, N., & Landén, M., “Long-term follow-up of transsexual persons undergoing sex reassignment surgery: Cohort study in Sweden” *PLoS One* 6 (2011), e16885. See also Richard P. Fitzgibbons, “Transsexual Attractions and Sexual Reassignment Surgery: Risks and Potential Risks” *Linacre Quarterly* 82.4 (2015): 337-50; Walt Heyer, “50 Years of Sex Changes, Mental Disorders, and Too Many Suicides” *The Public Discourse* <http://www.thepublicdiscourse.com/2016/02/16376/> (accessed 5/2/2016). In particular, Heyer cites a 2004 study of “100 international medical studies of post-operative transsexuals by the University of Birmingham’s aggressive research intelligence facility (Arif)” that “found no robust scientific evidence that gender reassignment surgery is clinically effective” <http://www.theguardian.com/society/2004/jul/30/health.mentalhealth> (accessed 5/2/2016).

³² Dan Hitchens, “What’s the truth about transsexuality?” *Catholic Herald* <http://magazine.catholicherald.co.uk/magazi>

[ne-post/whats-the-truth-about-transsexuality/pugpig_index.html](#) (accessed 5/3/2016).

³³ To be clear, the point of these analogues is only that someone can believe someone about the very core of their being and yet, potentially, be objectively wrong about it.

³⁴ Our anthropological analysis clearly indicates a positive obligation to provide tailored psychological and psychoanalytic treatment as well as social support for patients in each category. These methods of non-invasive intervention are, at minimum, more clearly congruent with the exhortation found in the *Catechism* to come to terms with one's sexual identity as it is given by God. A Christian anthropology affirms that surgery is not required to attain the threshold for membership or acceptance in the human moral community.

³⁵ This, for instance, is referred to as the "feminine essence" narrative in male-to-female transsexuals. See J. M. Bailey and K. Triea, "What many transgender activists don't want you to know: and why you should know it anyway" *Perspectives in Biology and Medicine* 50.4 (2007): 521-34.

³⁶ Such would be an argument premised upon "brain sex" theory.

A Bitter Pill: Prescription Drug Costs and Direct-to-Consumer Advertising

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Anyone who watches TV is aware of the dramatic proliferation of direct-to-consumer advertising (DTCA) of prescription drugs (I've noticed that these ads only appear on stations whose demographic includes me. Presumably, millennials are not buying many drugs for urinary urgency or ED). Research shows that total DTCA in the United States (New Zealand is the only other country that allows it) totaled only \$12 million in 1989; it reached \$350 million five years later, tripled by 1998, doubled to \$2.24 billion by 1999 (after the FDA relaxed its advertising rules) and doubled again by 2005.¹

Not all of these ads are the same. The FDA describes three general categories. One the "help-seeking ad" which provides "only information about a medical condition and encourages patients to contact their physician." These ads do not mention a specific product. A second category is "reminder

ads" which include the product name and may provide information about "strength, dosage form, or price, but...[don't] mention indication or make any claims." The third category is a "product claim ad" which mentions the name, the indication, and makes claims about efficacy or safety.² Most of the ads we see on TV today are of this third kind.

DTCA raises several different ethical questions, most of which are subsets of principles related to marketing in general: efficacy, side-effects or limitations of the product, value, truthfulness of claims about benefits, and cost. The matter is further complicated because many ethicists consider drugs (and health care in general) are not just another product but rather "special goods [that] are different from others in the market place." If prescription drugs are in a different category from tires, snowblowers or beer, then the ethical bar for advertising must be raised higher for them.

A review of the literature on DTCA reveals several specific ethical hazards: overselling, over-pricing, re-pricing, informed consent, and the impact on the role of the physician. In addition, these questions must be examined at both a micro and a macro level, since the cost of drugs affects individual

patients as well society's ability to allocate a certain percentage of our total health care dollars to drugs as opposed to other kinds of therapies.

Overselling

This is related to truthfulness in claims about the efficacy of a drug which involve both promises and disclaimers. Even though DTCA has been guided since 1985 by an FDA requirement for a “fair balance” of information³ and “brief summaries” of drug benefits or side effects, ads sometimes overestimate benefits or underplay risks by visual images of happy, carefree patients that do not reflect the seriousness of side effects or even of the illness itself.⁴ In their article on the “vernacular of risk,” Greene and Watkins note the difficulty of conveying risks to patients by means of technical information printed in tiny type on a package insert. Indeed, they describe early attempts to be “virtually useless” as information sources.

Another aspect of overselling is creating or identifying a “new” disease and then marketing a drug that will treat it. The most familiar example is Viagra and other treatments for “erectile dysfunction.”

Overpricing

There has been a great deal of publicity about the high cost of prescription drugs, especially those designed for relatively rare diseases. A recent study by the Kaiser Family Foundation says that the high price of drugs is the public's top health care priority⁵. The American Medical Association recently called for a ban on consumer advertising of prescription drugs, saying that “marketing costs play a role in fueling escalating drug prices,” and that “patient care can be compromised when prescription drugs are unaffordable.”⁶ Ezekiel Emmanuel notes that Cerezyme for Gaucher disease (a genetic disorder that causes fat accumulation in organs) and Kalydeco for cystic fibrosis both cost about \$300,000 per year – or almost \$1,000 a day – and have to be taken for the rest of the patient's life. One author describes her own personal experience of seeing the price of Gleevec rise from \$3000 to \$9000 per year between 2007 and 2015.⁷

The price of prescription drugs continues to rise, with the list price rising faster (12% last year) than the net price (the price insurers and employers pay). The latter was only 2.8%. This sounds like good news, but the unintended consequence is that those who might actually end up paying the full list price are often the uninsured or unemployed, who do not have the leverage of volume purchasing. “It's sort of

embedded in the health care system that the price is never the price, unless you're a cash-paying customer, and in that case we soak the poor," says Adam J. Fein.⁸ This should be a major concern to those in Catholic health care if we claim to be advocates for the poor.

Another aspect of overpricing is packaging. In a move that resembles selling 20-ounce bottles of soda to people who only want to drink 12 ounces or selling a package of chips at the same price, even though it contains 10% less product than it used to, some cancer drug manufacturers effectively sell more drug than a patient needs by marketing only one vial size. This results in waste and raises cost.⁹

Other manufacturers have attempted "differential pricing"¹⁰, in which they sell drugs at different prices in different countries in line with the income levels in those countries. Some have cost assistance programs (e.g., "If you have trouble paying for your medication, call us, we may be able to help"), but one researcher says "The public relations benefits [of these programs] for drug companies may outstrip the actual improvement in medical outcomes for patients."¹¹ Another maintains that these offers are designed to make companies look generous so "patients won't complain about the ridiculously unsustainable prices because they won't see them, which in turn allows prices to continue to rise."¹² In addition, only a small percentage of

eligible patients appears to take advantage of these offers, and there is evidence that getting such help is cumbersome and time-consuming.¹³

Repricing is a slightly different issue. It occurs when a manufacturer buys a generic, unpatented drug, patents it, and sells it at an enormously inflated price. This is what happened recently when Martin Shkreli of Turing Pharmaceuticals bought the rights to Daraprim, which treats toxoplasmosis, and raised the price from \$13.50 to \$750 per tablet.

Value-based Pricing

Products that perform better are usually more expensive. However, benefit and value are often subjective, and especially so in health care. The benefit of surgery or chemotherapy to me may be a clear burden to someone else. Some drugs, such as Opdivo, promise to add time – about 3.2 months on average -- to a lung cancer patient's life. The problem is that it costs about \$150,000 per year for treatment. Of course the problem here is not the high price, but the patient's perception of the value of an additional 3.2 months. How much is that time worth? This calculation is much easier if someone else -- a private insurer, Medicaid or Medicare -- is paying the bill.

There have been some efforts to establish value-based pricing on prescription drugs, i.e., paying

more for drugs that have fewer side effects or better indications of effectiveness. If this were the case, the widely advertised Jublia, a topical medication for toenail fungus, wouldn't fare too well. A full 48-week course of treatment could cost over \$10,000. The fact that it is fully effective in only 20% of patients is not mentioned in its ads¹⁴. As researcher Peter Bach says, "A drug that works is worth something. One that doesn't is not. If a new drug works no better than an older one, the two have equal worth. If a drug costs a lot, that's OK only if it makes people so healthy that it reduces their spending on other forms of health care."¹⁵

The problem of assessing value and truth claims is exacerbated because ethics and compliance have not kept pace. Although the FDA regularly sends "warning letters" to pharmaceutical companies that stray too far, the number of FDA employees falls far short of what is necessary for adequate monitoring. Indeed, the \$4.8 billion spent by big pharma on DTCA in 2006 is more than double the entire budget of the FDA.¹⁶

Informed Consent

Informed consent is at the heart of ethical medicine. There is little doubt that DTCA provides more information to patients, both about the drugs and about other treatment options. The question is whether there is enough information about the

drug's benefits and side-effects and whether the patient is able to understand that information well enough to make a good choice. Does DTCA really improve patients' understanding of their conditions, or is it designed primarily to influence doctors' prescribing choices? Some researchers believe that DTCA makes patients more informed, more involved and even more compliant. Others fear the risk of misinformation and manipulation is too high.

"Relationship marketing" affects informed consent. It is designed not just to generate a one-time sale, but to create an enduring relationship with the patients so as to create a steady revenue stream. As Alford and Naughton note, the purpose of relationship marketing is "to establish, maintain and enhance (usually but not necessarily long term) relationship with customers and other partners, at a profit, so that the objectives of the parties involved are met. This is achieved by mutual exchange and fulfillment of promises."¹⁷

A strong relationship between health care providers – even a pharmaceutical company – is ordinarily a good thing. In fact, one of the great weaknesses of our current health care system is lack of a medical home and the relationship that goes with it. However, if the relationship is structured for the provider's benefit, then its value to the patient may decline. The ethics of "relationship marketing"

must be measured against an authentic understanding of the virtue of solidarity, by which we are bound to others by virtue of our membership in the human community. Clearly ethical business practices are based on solidarity; cheating, fraud and deception are violations of it. Such practices place self-interest above the value of the human relationship. Relationship marketing can easily short circuit so that we “skim over the fundamentals of relationship building on our rush to cash in on the potential rewards of creating close connections with our customers.”¹⁸

Physician-Patient Relationship

The most dramatic change brought about by DTCA is the change in the relationship between the physician and patient. Until recently, the physician was the exclusive mediator between the patient and prescription medications. Few patients would even have *known about* specific medications, let alone had the nerve to request them by name.

Pharmaceutical companies avoided direct marketing until the 1970s because they did not want to be associated with “patent medicine” which was sold over the counter without a physician’s advice. Early ads referred patients to physicians because physicians gave their products legitimacy. While some physicians feel DTCA gives patients more information and more control, others find it to be

an unwarranted intrusion into their relationships, especially if patient requests are ill-advised or uninformed.

Financial incentives can impact the role of the physician as well. Although pharmaceutical companies cannot pay physicians directly for using their products, they can pay consulting or lecturing fees. These are publicly disclosed.

Currently Medicare pays doctors the average sales prices of a drug, plus a 6% commission. This means that more expensive drugs generate more revenue for the physician. In March of 2016, Medicare announced it was setting up a trial to eliminate this “perverse incentive” to prescribing more expensive drugs by reducing commissions on more expensive drugs and instituting a flat fee for whatever drug is prescribed.¹⁹ If it works, it will become the new standard.

Conclusion

The debate about direct-to-consumer advertising is a complex one that involves health care economics, public policy, marketing, health outcomes, patient autonomy and health care disparities. Supporters of DTCA say that it educates and empowers patients, encourages patients to contact a physician, strengthens the doctor/patient relationship, reduces under-diagnosis and under-treatment, removes the

stigma associated with some diseases and encourages competition and lower prices. Opponents say DTCA can encourage overutilization, overemphasis on benefits, expose patients to risks that may not be known, and leads to inappropriate prescribing, increased cost, and tension between the patient and physician.

I have only drawn attention to a few of the most prominent issues. I have not addressed the ownership of drugs and drug research and the ways in which we try to protect pharmaceutical intellectual property rights. This important question deserves its own thorough treatment.

Rising expenditures on drugs and health care in general make it certain that both policy and ethical evaluation will continue to evolve.

¹ Two studies cite the same statistics. C. Lee Ventola, “Direct to Consumer Pharmaceutical Advertising,” *Pharmacy and Therapeutics* (October 2011): 669-674, 681-884; and Jeremy A. Greene and David Herzberg, “Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the 20th Century,” *American J of Public Health* (May 2010): 793-803. It is important to note that while spending on DTCA has increased dramatically, it is still a relatively small percentage of pharmaceutical promotion overall. Much more is still spent on traditional marketing to physicians, which is often a combination of promotion and education.

² Ventola, “Direct to Consumer.” See also Greene and Herzberg, who track the graduation evolution from general ads in the early 20th century which simply linked the manufacturer to praiseworthy qualities and professionalism (to distance themselves from less respectable “patent” medicines) to the much more detailed ads we see today. Further information about FDA advertising categories found at www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm. Accessed March 21, 2016.

³ Jeremy Greene and Elizabeth Watkins, “The Vernacular of Risk – Rethinking Direct-to-Consumer Advertising of Pharmaceuticals,” *NEJM* (September 17, 2015): 1087-89. See also Ventola, for a fuller description of the history of direct to consumer advertising.

⁴ Ventola, 15, at “Overemphasizes Drug Benefits.”

⁵ “Prescription Drug Costs Remain Atop the Public’s National Health Care Agenda, Well Ahead of Affordable Care Act Revisions and Repeal,” KFF news release, October 28, 2015, <http://kff.org/health-costs/press-release/prescription-drug-costs-remain-atop-the-publics-national-health-care-agenda-well-ahead-of-affordable-care-act-revisions-and-repeal/>, accessed March 21, 2016.

⁶ American Medical Association, “AMA Calls for Ban on Direct to Consumer Advertising of Prescription Drugs and Medical Devices,” news release, November 17, 2015, accessed March 21, 2016.

⁷ Erin Havel, “Name Brand Drugs Costs Are Too High and Generics Are Growing Out of Reach,” <http://www.huffingtonpost.com/erin-havel/name->

[brand-drug-costs-are-too-high-and-generics-are-growing-out-of-reach_b_9161066.html](#), accessed 3/21/2016.

⁸ Mr Fein is quoted by Katie Thomas, “Drug Prices Keep Rising Despite Intense Criticism”, *New York Times* (April 26, 2016). Andrew Pollack cites a similar problem that arises from an attempt in California to keep state programs from paying more for any drug than the Veteran’s Administration does (they get a favorable rate). Again, it sounds good, but AIDS advocacy groups are wary, claiming that lowering the price paid by the state might increase the cost for others. The article notes that lack of transparency in pricing is a major problem. “California Drug Price Plan is Criticized by Patient Advocates,” *New York Times*, July 4, 2016.

⁹ Gardiner Harris, “Waste in Cancer Drugs Costs \$3 Billion a Year”, *New York Times*, March 1, 2016, citing a study done by Memorial Sloan Kettering Cancer Center and published in February by the *British Medical Journal*.

¹⁰ Sara Parker-Lue et al, “The Ethics and Economics of Pharmaceutical Pricing,” *Annual Rev of Pharmacol and Toxicol* (2015:191-206) at 199. This article presents an excellent overview of several ethical issues in pharmaceutical pricing.

¹¹ *Ibid.*, 195.

¹² Erin Havel, “Name Brand Drugs Costs Are Too High”.

¹³ Parker-Lue et.al., 195.

¹⁴ Jublia’s website indicates that 15-18% of patients achieve complete cure after 48 weeks of treatment.

<http://www.jubliarx.com/efficacy-side-effects>, accessed March 21, 2016.

¹⁵ “A New Way to Define Value in Drug Pricing,” *NEJM Catalyst*, February 24, 2016. Cites “DrugAbacus” which enables patients to make a more objective assessment of value.

¹⁶ Greene and Herzberg, “Hidden in Plain Sight,” 801.

¹⁷ *Managing As If Faith Mattered*, p. 183, quoting C. Gronroos. Relationship marketing is the result of trying to replace the “4 Ps” of marketing (product, price, place, promotion) with “4 Cs” (consumer need, consumer cost, convenience and communication, [p. 188]).

¹⁸ Alford and Naughton, 184-185, quoting S. Fournier et al, “Preventing the Premature Death of Relationship Marketing.”

¹⁹ Margot Sanger Katz, “Medicare Tries an Experiment to Fight Perverse Incentives,” *New York Times*, March 10, 2016.

Q&A on the 'Unplanned Pregnancies' of the Catholic Church

This month the Vatican released its latest reflection on what some people call the “new movements” in the Catholic Church. The document, titled *Iuvenescit Ecclesia* (The Church Rejuvenates), was prepared by the Congregation for the Doctrine of the Faith. It attempts to discuss the relationship between the hierarchy and newly formed lay movements. The CDF acknowledges the movements as a “great source of renewal” and recognizes their ability to “fill the heart of the Church with joy and gratitude.”

However, the document is truly designed to warn these movements to not become a “parallel church” outside the authority of the hierarchy. “To be Catholic, it argues, means in part accepting the authority of the bishops and the pope, and seeking their official recognition.” In the end, the document actually asks both the hierarchy and the new movements to give a little in order to work together peacefully. The document says that the hierarchy must avoid “juridical straitjackets that deaden the novelty which is born from the specific experience.” Meanwhile the new movements have to avoid “running parallel to ecclesial life or not [seeing themselves as] ordered in relation to the hierarchical gifts.” John L. Allen Jr., *Cruxnow.com*, June 14, 2016

Love, Not Some Idea of Perfection, Leads to Happiness, Pope Says

"The world does not become better because only apparently 'perfect' -- not to mention fake -- people live there, but when human solidarity, mutual acceptance and respect increase," the pope said June 12 celebrating Mass for the Year of Mercy Jubilee. The Mass included individuals with Down Syndrome as well as altar attendants and lectors with disabilities.

During the Gospel story about the sinful woman who washed Jesus' feet, actors portrayed the scene while sign language interpreters were stationed throughout the square. "Each of us, sooner or later, is called to face -- at times painfully -- frailty and illness, both our own and those of others," Pope Francis said in his homily. "In an age when care for one's body has become an obsession and a big business, anything imperfect has to be hidden away, since it threatens the happiness and serenity of the privileged few and endangers the dominant model," the pope said. "In some cases, we are even told that it is better to eliminate them as soon as possible, because they become an unacceptable economic burden in time of crisis."

Prior to the Mass, the pope held a special audience for participants in a conference on catechesis for

disabled persons. One person asked the Pope Francis how parishes can fight discrimination and welcome individuals with disabilities. The pope replied acknowledging the fear that can arise by encountering someone who is different, however, "Differences are a richness because I have something and you have something else and by putting the two together we have something more beautiful, something greater." Cindy Wooden, *Catholic News Service*, June 12, 2016

Details on Death Certificates Offer Layers of Clues to Opioid Epidemic

Dr. James Gill works for a morgue in Farmington, Connecticut. Recently his office has had to increase storage space due to a 50 percent increase in autopsies. On one day, the morgue had nine bodies, "four were the remains of the people who likely died from an accidental drug overdose. A fifth was a probable suicide involving drugs."

Dr. Gill is striving to gain more data on "exactly which drugs killed exactly which people." He recounts the story of a mother who called to learn more information about her daughter's overdose death.

"Can you tell me, did she suffer?" the woman wanted to know. "Was she in pain?" "And I explained to her," Gill said, "that, with an opioid

death, the person just gradually goes to sleep and it's very painless. "And she started crying," Gill said. "And it gave her some comfort."

Gill believes the first step is a change in the way we fill out death certificates. "A death certificate needs to say more than something vague like 'opioid intoxication' to help both law enforcement and public health officials curb the distribution and hopefully abuse of opioids." Doctors need to write more than "acute of multi-drug intoxication." They need to write which drugs actually caused the death.

So far states decide exactly how to approach this topic. Some are better than others at recording drug information for data collection. Meanwhile, families may not want "heroin overdose" or "vicadin abuse" on their family member's death certificate. What is known is that the rise in drug induced deaths requires a multi-prong approach and the first step is to recognize and name the actual culprits. Jeff Cohen, *Los Angeles Times*, June 1, 2016

Doctor-Assisted Suicide Legal in California Started June 9

The California End of Life Option Act took effect on June 9th. The law permits a terminally ill adult in California with a life expectancy under six months to get a prescription for a lethal dose of certain drugs. The bill was signed by Governor Jerry Brown

back in October. It makes California the 5th state to legalize doctor-assisted dying.

“The Life Option Act requires that a patient seeking lethal drugs make three formal requests to their attending physician: one written and two of them orally delivered and spaced at least 15 days apart. The law also requires informed consent and excludes children. The lethal drugs must also be self-administered.” What lingers is the question of who and how many people will utilize this law.

Jacob Gershman, *Wall Street Journal*, June 8, 2016

Government Seeks Limits on Short-Term Health Policies

The Obama administration is seeking to limit short-term health policies that include features currently banned under the Affordable Care Act. These plans usually do not cover pre-existing conditions. The proposal will create rules for such policies including limiting them to three months or less, and prohibiting individuals from renewing coverage at the end of the period. The proposal closes a gap which allowed healthier consumers to purchase these cheaper plans and remain on them for up to a year. The Administration hopes that by limiting these plans, healthier individuals will enter the ACA marketplace and slow down the need to raise premiums. Anna Wilde Mathews, Louise

Radnofsky, and Stephanie Armour, *Wall Street Journal*, June 8, 2016

Congress Leaves for Recess Without Zika Funding

The 52-44 vote on the motion to limit debate on the \$1.1 billion anti-Zika funding bill amounted to a last-minute attempt by Senate Majority Leader Mitch McConnell to move the legislation to the president's desk with the chamber ready to leave for a seven-week summer recess. Sixty "aye" votes were required to advance the measure.

<http://www.rollcall.com/news/policy/final-zika-vote-expected-senate-no-signs-deal#sthash.pF7YczrI.dpuf>

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Assistant Director, supervised the contributions of health law students Erin Grant (J.D./M.H.A. anticipated 2018) and Ryan Williams (J.D./M.H.A. anticipated 2017).

HHS Cracks Down on Short-Term Health Plans, Tweaks Risk Adjustments

The Department of Health and Human Services has issued new proposed regulations, limiting the availability of less-expensive short-term health plan options on insurance exchanges. The plans

addressed in these new regulations do not meet the requirements for qualified health plans under the Affordable Care Act (ACA); for example, plan premiums may be based on pre-existing conditions of the insured. Following enactment of the ACA, insurers continued offering these short term plans—designed to cover only short-term gaps in insureds’ coverage—with the option to continually renew the “short term” coverage. The new proposed regulations address this pattern, limiting the duration of such policies to a maximum of three months without the option to renew the coverage. In addition, insurers must notify the insured under these policies that they owe a tax penalty as the policy does not comply with the mandate established under federal law. The limitation addresses the loophole offered by short-term coverage, incenting consumers toward the purchase of plans that meet the federal standard. Health policy interest groups interviewed suggest that the new regulations might particularly affect healthier, young adult insureds who have not utilized health plans offered on insurance exchanges at the predicted rates. Virgil Dickson, *Modern Healthcare*, June 8, 2016

<http://www.modernhealthcare.com/article/20160608/NEWS/160609920/hhs-cracks-down-on-short-term-health-plans-tweaks-risk-adjustment>

Missouri Throws First Big Wrench into Aetna-Humana Deal

Missouri is the first state to take issue with the potential Aetna-Humana currently pending approval from the Department of Justice. John Huff, the director of the Department of Insurance for the State of Missouri issued a preliminary order against the Aetna-Humana deal on May 25, 2016. Per the order, the proposed merger would result in anticompetitive effects. Should the merger be approved, Aetna and Humana would not be permitted to sell particular Medicare Advantage products in the state, and individual Medicare Advantage plans would be barred from being sold in rural counties. Aetna released a statement following the order, noting hope for further dialogue with state officials and emphasizing that the merger was still being investigated by the U.S. Department of Justice. The DOJ did not comment. Aetna and Humana now have thirty days to submit a proposal to mitigate anticompetitive effects which might result from the deal. Such a solution would likely involve divestiture of Medicare Advantage assets in certain locales with heightened anticompetitive activity. Even with such a proposal, commentators expressed skepticism that divesting of assets would remedy the antitrust concerns at issue. Bob Herman, *Modern Healthcare*, May 25, 2016 <http://www.modernhealthcare.com/article/20160525/NEWS/160529950>

N.J. Hospitals Lose Court Challenge of Tiered Horizon Health Plan

A New Jersey appeals court reached a decision in a litigation action brought by ten hospitals. The state's Department of Banking and Insurance allowed the state's dominant insurance provider (Horizon Blue Cross and Blue Shield) to divide healthcare providers into two tiers with disparate out-of-pocket costs. The hospitals bringing the action had been placed into the lower tier, which consequently would result in higher out-of-pocket costs for patients. Plaintiffs argued that the state government's allowance of the tiered system was arbitrary, capricious, and unreasonable.

Additionally, the hospitals expressed concern for the financial health of their institutions—and others similarly situated in the lower tier—who could lose patients to their higher-tiered competitive. The appellate court ruled against the hospitals, holding that use of the tiered system was not arbitrary, capricious, or unreasonable. Lisa Schenker, *Modern Healthcare*, June. 7, 2016

<http://www.modernhealthcare.com/article/20160607/NEWS/160609923/n-j-hospitals-lose-court-challenge-of-tiered-horizon-health-plan>

Pfizer Blocks the Use of Its Drugs in Executions

Pharmaceutical firm Pfizer announced its intent to place distribution limits on some of its products,

preventing them from being used in lethal injections for capital punishment. The drugs in question will continue to be produced, as they are also distributed for medical use. However, Pfizer will restrict the sale of seven drugs to selected wholesalers.

Distributors must certify that they will not resell the product to corrections departments and will be monitored for compliance. Many other European and American pharmaceutical firms have taken similar actions in recent years due to pressure from human rights groups. This wave of limitations from pharmaceutical firms has made it difficult for death-penalty states to obtain these drugs. This has led some states to postpone executions or covertly import drugs from sources abroad. Additionally, some states are experimenting with new combinations of drugs for lethal injections or looking to other means of capital punishment. In instances where lethal injections drugs are able to be obtained, death penalty states are not disclosing the source of the drug, either an effort not to inform manufacturers of the product's misuse or to shield suppliers from backlash from opponents of the death penalty. Erik Eckholm, *The New York Times*, May 13, 2016

http://www.nytimes.com/2016/05/14/us/pfizer-execution-drugs-lethal-injection.html?_r=0

Justices, Seeking Compromise, Return Contraception Case to Lower Courts

In a per curiam decision, the eight Justices of the U.S. Supreme Court have remanded one of the higher-profile cases of this term to the lower courts—making clear that the decision expresses no views on the merits of the legal issues. The case, *Zubik v. Burwell*, involved the Affordable Care Act’s contraceptive mandate, which had previously been at the center of *Burwell v. Hobby Lobby* from the 2014 term. In the case, the petitioner religious employers argued that the accommodation allowing them to opt of providing contraceptive coverage to their female employees was not truly an accommodation as offering contraceptives in any way through their health plan infrastructure made them complicit in the behavior they consider to be morally objectionable. The court’s decision does not result in a holding for either party and comes amid political deadlock to fill the seat on the Court left vacant by the death of Justice Antonin Scalia. This ultimate result was foreshadowed by an unusual order from the court following the oral argument for the case in March, in which the court called for additional briefing from both sides to “address whether and how contraceptive coverage may be obtained by petitioners’ employees through petitioners’ insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees.” In this per curiam decision the Court noted that as a result of this supplementary briefing,

both the petitioners and the government have confirmed that such a scenario is a feasible reality. This result allows lower courts to direct parties to seek this compromise without establishing binding precedent—freeing the Supreme Court to potentially rule on the issue at a later time. Adam Liptak, *The New York Times*, May. 16, 2016 <http://www.nytimes.com/2016/05/17/us/supreme-court-contraception-religious-groups.html>

U.S. Supreme Court Endorses Theory That Could Expand False Claims Act Liability

In a unanimous opinion on June 16, written by Justice Clarence Thomas, the Supreme Court allowed for the potential to bring False Claims Act (FCA) cases against healthcare providers under a theory of “implied certification”. In *Universal Health Services v. Escobar*, the Court ruled that FCA liability may be imposed via a theory of implied certification where payment is requested for specific representations about goods or services provided and where an organization’s failure to disclose non-compliance with “material requirements would equate to misleading half-truths”. The decision is viewed by some as an attempt by the court to fight healthcare fraud while also limiting providers’ FCA liability exposure. The case has been remanded to the appellate court, but endorsed the idea that

healthcare providers might be subject to FCA liability where they providers violate some Medicare and Medicaid rules that are not related to conditions of payment. The qualitative standard discussed in the opinion establishes categories of conduct where FCA liability can be imposed; however the court also noted that the FCA “cannot be used as a vehicle for punishing garden-variety breaches of contract or regulatory violations.”

Aurora Aguilar and Bob Herman, *Modern Healthcare*, June 16, 2016

<http://www.modernhealthcare.com/article/20160616/NEWS/160619930/u-s-supreme-court-endorses-theory-that-could-expand-false-claims-act>

Transition from Volume-Based to Value-Based Care Slower than Predicted

The transition of Medicare reimbursement payments from a volume-based system to a value-based system has been “sluggish.” Health and Human Services (HHS) recently reported that fewer than twenty-five percent of hospitals are on schedule to provide half of their patient care through a value-based system by 2018. The original targets set by CMS anticipated that, by 2016, thirty percent of traditional payments would be tied to quality or value of the patient care provided, and eighty-five percent of Medicare payments; in fact, only three percent of providers are on schedule for the targets set by CMS, and only twenty-three

percent are expected to meet targets by 2019. A health system survey of 190 hospitals revealed that sixty-two percent of hospitals have less than ten percent of their care tied to value-based payments. Smaller hospitals were even less likely to have switched, because of insufficient capital to take on the risk required in value-based care. This exemplifies one of the biggest barriers for hospitals; a switch to value-based care requires a vast amount of patient data to identify, manage, and predict the cost of high-risk patient populations, as well as significant financial reserves for the hospital to effectively target and treat these costly populations. Still, HHS remains optimistic. The agency reported that as of this year, thirty percent of Medicare payments are currently tied to quality or value of care provision, as value-based reimbursements currently equal one-third of all Medicare reimbursement spending. This is ahead of the target set by CMS, originally to be reached at the end of 2016. Rajiv Leventhal, *HealthCare Informatics*, June 9, 2016

<http://www.healthcare-informatics.com/news-item/payment/health-catalyst-hospitals-progressing-sluggishly-toward-hhs-value-based-0>

2017 Insurance Premiums Predicted to Rise

A new study by the Kaiser Family Foundation (KFF) predicts that health insurance premiums will rise in 2017 faster than in previous years to date,

with the cost of the second-lowest silver plans expected to increase by an average of ten percent, compared to five percent in 2016. The lowest-cost silver plans are expected to increase by an average of eleven percent, with the highest increases occurring in Oregon at twenty-six percent, and the lowest in Rhode Island at a decrease of fourteen percent. However, many of the plans which offered the lowest-priced plans in their category in 2016 will not offer the lowest-priced plans in the same category this year, which means that enrollees may have to switch providers to maintain similar premium payments. For example, though Blue Cross Blue Shield offered the lowest premium in the second-lowest silver plan category last year in Providence, Rhode Island, it no longer does; the lowest premium in that category is now provided by Neighborhood Health Plan, while BCBS's lowest-priced plan in the category will see premiums increase by about twenty percent. Additionally, fewer insurers will be participating in the marketplace, in notable part due to UnitedHealth's withdrawal from public exchanges. This will likely impact premium prices in the individual market, though it remains to be seen how much prices will change. Cynthia Cox, et. al., *Kaiser Family Foundation*, June 15, 2016

http://kff.org/health-reform/issue-brief/analysis-of-2017-premium-changes-and-insurer-participation-in-the-affordable-care-acts-health-insurance-marketplaces/?utm_campaign=KFF-2016-June-

ACA-Marketplace-Premiums&utm_source=hs_email&utm_medium=email&utm_content=30598647&_hsenc=p2ANqtz-9i5jC4iCpE4-9-YusMvaZBu75DYceUGpr5oPhIBPoRKPmYUwnxVQkbBguF6zXPoPqv0IOYTNghwR-RHg5ddr_vxLL4CA&_hsmi=30598647

Continuing Healthcare Reform: The Latest Proposal by Speaker Ryan Challenges Our Current System

Over past Presidential administrations, much healthcare reform debate has centered over who should control individuals' cost-related decision-making: Consumers, or the federal government. The Bush administration emphasized consumer-driven healthcare, which envisioned patients making crucial decisions related to their healthcare costs and service options. The Obama administration countered that these decisions were too complex for patients to make on their own, creating regulators to control consumer options. The latest healthcare reform plan, presented by House Speaker Paul Ryan, shifts the focus back to consumers. Though it retains the Affordable Care Act's foundational premise of universal access to care, the Ryan Plan calls for expansion of health savings accounts, increased insurance portability, and more service choices that depend on what

consumers are willing to spend. The proposed plan would allow a refundable tax credit for consumers who do not have access to coverage through their employer or federal programs like Medicare. This credit, which would rise with healthcare costs, would adjust for age to allow older Americans to receive appropriate care. The Ryan plan, however, loosens regulations on what plans may offer. Instead of requiring credits to be used in healthcare exchanges, consumers may use these credits on any qualified health plan, increasing insurer competition and lowering costs. If consumers do not spend their full credit on a plan, the excess is deposited into a spending account used for out-of-pocket expenses. Ultimately, the Ryan Plan seeks to provide greater consumer autonomy and increased competition in healthcare, while still retaining universal access to care. Thus, the healthcare debate is shifted from universal access to who should decide how individuals spend their healthcare dollars.

Scott Gottlieb, *Forbes*, June 22, 2016

<http://www.forbes.com/sites/scottgottlieb/2016/06/22/paul-ryans-healthcare-plan-re-challenges-a-central-tenet-of-obamacare/#77a0b3f07c45>

Medicare and Social Security Remain Top Priorities for Upcoming Presidential Administration

Earlier this June, the Obama administration announced that the financial outlook for Medicare

had deteriorated over the past year, and that Social Security continues to face a dim financial prognosis. Financial leaders hope this announcement will influence the current Presidential candidates to take a stronger position on financial reform of these programs. Hillary Clinton has proposed increasing Social Security benefits and increasing participation in Medicare by allowing younger populations to “buy in” to the program, while Donald Trump has said he will not cut either program. Under current law, Medicare will exhaust its funds in 2028, and Social Security could be depleted by 2034. The worsened outlook for Medicare has resulted due to changes including a higher service usage rate than anticipated, lower worker productivity and decreased tax revenue. Costs of Medicare and Social Security are projected to grow faster than the economy, resulting partially from the increasing healthcare needs of aging Baby Boomers and increasing costs of expensive prescription drugs. President Obama has approached this issue by calling out to the nation’s highest earners to contribute more to the program through taxes. Last year Congress also passed a law to provide a short-term fix to Social Security’s disability trust fund, extending the depletion of the trust fund by seven years to 2023. Still, the “future financing gap” in Social Security remains an issue that will need to be discussed as dependency on the program grows.

Robert Pear, *New York Times*, June 22, 2016

http://www.nytimes.com/2016/06/23/us/politics/medicare-social-security-trustees-report.html?rref=collection%2Ftimestopic%2FHealth%20Care%20Reform&_r=0

MACRA Likely to Accelerate Trend in Healthcare Consolidation

April 2015 brought about one of the largest historical changes in physician reimbursement as the traditional fee-for-service method was replaced by the Medicare Access and CHIP Reauthorization Act, or MACRA. This new method is more consistent with the Center for Medicare and Medicaid's (CMS) push for care that is reimbursed based on quality of patient outcomes rather than volume. Under MACRA, this is accomplished through physician participation in alternative payment models (APM) of care, which hold physicians accountable for the quality and value of care provided. Now, healthcare leaders are beginning to see the implications of this legislation. First, it will create more predictability in how physicians are paid for their services. Also, and perhaps an unintended consequence of MACRA, implementation may lead to consolidation. Small and midsize practices do not currently have the administrative capabilities to comply with the vast reporting requirements, or the financial reserves to support the risk-based requirements, under MACRA, and so it is likely that these providers will

seek to join larger provider groups or health systems to survive. This will likely accelerate the trend in healthcare consolidation. At the same time, rapid consolidation has already stirred tensions with existing antitrust legislation. Earlier this year, a judge ruled against the Federal Trade Commission's effort to block a merger between Penn State Hershey Medical Center and PinnacleHealth System in Pennsylvania, noting the "irony" that the same federal government that created the FTC to prevent economic monopolies also created a climate "that virtually compels institutions to seek alliances." Still, the biggest question remains how the impending aggregation of health systems will impact the cost of healthcare for consumers. Joseph Fifer, *Modern Healthcare*, June 25, 2016
<http://www.modernhealthcare.com/article/20160625/MAGAZINE/306259979/commentary-macra-likely-to-accelerate-consolidation-will-the>

Health Care Ethics USA

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Upcoming Webinar

Preparing for the Ethics of Population Health:
Our Moral Tradition Considered Anew

Oct. 25, 2016

Noon - 1:15 p.m. ET

Presenter:

Michael Rozier, SJ, MPH
Doctoral Candidate, Health Management and
Policy University of Michigan
Ann Arbor, Mich.

Population health is increasingly important in U.S. health care in light of the Affordable Care Act and widespread acceptance of the Triple Aim framework from the Institute of Healthcare Improvement that calls for improving patient experience, advancing population health and reducing the per capita cost of care.

This presentation will explore ways in which the Christian and Jewish traditions have framed concerns for the health of individuals and populations over time and how these moral resources/insights can guide us in 1) navigating the shift from clinical care to population health or 2) helping us pair our expertise in clinical care with contemporary needs for population health.



To learn more, go to chausa.org/calendar



We express our heartfelt gratitude
to our good friend and colleague

Sr. Patricia Talone, RSM, Ph.D.,

vice president, mission services of the Catholic Health Association, for her years of inspiration and sound counsel as associate editor of *Health Care Ethics USA*. Although Sr. Pat is retiring from CHA in August, she has made a lasting contribution to the editorial excellence and growth of *HCEUSA* as a valued resource for ethicists and senior leaders throughout the Catholic health ministry. We wish Sr. Pat well as she embarks on new opportunities to serve the ministry. We intend to enlist her as an author for future issues of *HCEUSA*.