

# An old principle in a new context

The doctrine of double effect using palliative sedation as an example

von Christof Breitsameter

Das alte Prinzip der Doppelwirkung fand in den letzten Jahrzehnten Anwendung in einem neuen Feld, nämlich dem der so genannten palliativen Sedierung. Der Beitrag zeigt jene Schwierigkeiten auf, die mit dieser Übertragung verbunden sind. Diese Probleme geben Anlass dazu, in diesem medizinischen Kontext nicht mehr auf das Prinzip der Doppelwirkung zu rekurrieren. Auch der Begriff der ‚indirekten Sterbehilfe‘, der ja auf dieses Prinzip Bezug nimmt, ist aufzugeben. Konsequenz kann nicht nur physisches Leid, sondern auch psychisches, existenzielles und spirituelles Leid prinzipiell als ein ethisch legitimer Grund für eine dauerhafte und tiefe Sedierung gelten, selbst wenn sie den Tod des Patienten beschleunigt.

## 1. Problem definition

The aim of this article is to examine the ethical valence of the principle of double effect with regard to palliative, primarily deep and continuous sedation for the purpose of pain control or symptom treatment. According to our empirical research, physicians are indeed guided in their decisions by the principle of double effect. This is because it is controversial in medical research whether deep and continuous sedation can have a life-shortening effect and it is therefore based on the fear that a medical intervention with a life-shortening effect could be associated with killing on request. Ultimately, this also affects so-called indirect euthanasia which makes use of the principle of double effect.<sup>1</sup> The principle of double effect also plays a role in literature on medical ethics in the context of palliative sedation; however, its treatment is not uniform, making a critical look worthwhile.

## 2. The background of the history of ideas

The doctrine of double effect was essentially developed by Thomas Aquinas when addressing the justification of killing a human being for the purpose of self-defense. The conceptual view is that the intended goal of the act is solely to save one's own life, while the killing of the opponent is merely accepted as a non-intended side effect of this act.<sup>2</sup> This is

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<sup>1</sup> The term indirect assisted suicide goes back to the "doctrine of double effect." According to this doctrine, an act with morally bad consequences can only be justified if these consequences are merely accepted as unavoidable side effects (*voluntarium indirectum*) of an intended, morally good main effect (*voluntarium directum*).

<sup>2</sup> By its nature, an act, even if it results in the killing of the aggressor, is an act of defence and not an act of killing. Of the two effects of such an act, self-defence is called an effect *per se*, and killing the aggressor is called an

based on the concept that an action is ethically legitimate if its intended goal represents a good, even if an evil is simultaneously brought about as an unintended side consequence. This concept is subject to several restrictive conditions: (1) According to this concept, the less harmful and equally effective alternative courses of action must have been fully exhausted.<sup>3</sup> (2) There must, of course, be at least two effects of a single act. (3) One effect has to pursue a good (*bonum*) (or to be ethically indifferent or neutral), another effect of the same act, on the other hand, has to produce an evil (*malum*), which is *known* but not *wanted*. (4) Moreover, the bad effect must not be an instrument to produce the good effect: The end does not justify the means. Overall, the harmful effect must be intended neither as an end nor as a means.<sup>4</sup> (5) Finally, as has already been emphasized with the reference to “as little harm” as far as possible, the means employed must be appropriate with regard to the effect to be achieved (means-end proportionality), and the advantages and disadvantages of the effects produced by such an action must be in reasonable proportion to each other (end-end proportionality).

The divergence of these two aspects initiates a first step of reflection. If it is an *absolute* good that must be defended, the determination of what is appropriate, in this case the availability of spare means required for it, is sufficient as a limiting factor.<sup>5</sup> If, on the other hand, the proportional weighing of goals is addressed, then goods are obviously treated as *relative* and weighed against each other. In the case of self-defense, this means: If one’s own life is in danger, the use of appropriate means for the purpose of self-defense is sufficient to make an ethically satisfactory assessment of the situation, because causing the external evil is not intended, only accepted, and is necessarily linked to the defense of one’s own life, which unequivocally represents a good. In more specific terms, this means that the

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effect *per accidens*. Therefore, it is possible to speak here of a *per se* good self-defence act; consequently, it is not a *per se* bad homicidal act. Therefore, the death of the aggressor must not be included in the intention of the acting party, the intention must be directed solely towards self-defence; cf. here, *Cordula Judith Scherer*, *Die per se schlechte Handlung in der Summa Theologiae des Thomas von Aquin. Die Bedeutung von Tugend und Gesetz für die Artbestimmung der menschlichen Handlung*, Bonn 2014, 259 f.

<sup>3</sup> With *Daniel P. Sulmasy*, *The last low whispers of our dead: when is it ethically justifiable to render a patient unconscious until death?*, in: *Theoretical Medicine and Bioethics* 39 (2018) 233–263, “reasonable and less risky alternatives” are discussed. Within risk, any expected damage is considered to be probable. This basically combines two determinations, which makes their comparability considerably more difficult, if not impossible, since an injury that is estimated to be minor but is highly likely to occur could be rejected in favor of an alternative that promises greater harm but is less likely to occur. An assessment of the consequences must therefore be supplemented, as we will discuss later, by an evaluation that cannot be made objectively but only subjectively, namely from the patient’s point of view. On the distinction between objective impact assessment and subjective impact evaluation, cf. *Christof Breitsameter*, *Medical decision making and communication of risks – an ethical perspective*, in: *Journal of Medical Ethics* 36 (2010) 349–352.

<sup>4</sup> Cf. *Daniel P. Sulmasy*, *Sedation and care at the end of life*, in: *Theoretical Medicine and Bioethics* 39 (2018) 171–180, here 174.

<sup>5</sup> Cf. *Kasper Raus; Sigrid Sterckx; Freddy Mortier*, *Can the doctrine of double effect justify continuous deep sedation at the end of life?*, in: *Sigrid Sterckx; Kasper Raus; Freddy Mortier (eds.), Continuous Sedation at the End of Life. Ethical, Clinical and Legal Perspectives*, Cambridge 2013, 177–201, here 180: “DDE (doctrine of double effect: CB) deals with relative wrongs, i. e., its application is limited to actions that are not clearly and absolutely wrong.” However, this is not correct because the point is to show that an absolute good is not intentionally violated. Therefore, two goods are not weighed against each other.

person causing harm may be harmed (only) to the extent that this is necessary for the defense of one's own life. Here, only the potential means, but not the ends, are weighed against each other.

At this point, it should be noted that the use of means, which must be ethically justified, breaks down into two aspects: on the one hand, it is a matter of alternative means, and on the other hand, of the gradual application of the very same means, whereby the comparison of alternative means has its purpose precisely in the graduation of their effects. In this respect, the *principle of parsimony*, which will be treated separately, can be described as an integral part of the principle of double effect. In other contexts however, Thomas Aquinas allows for the balancing of ends, for example, when it comes to justifying the theft of property in cases where a person's hunger can only be satisfied in this way and a need that threatens his existence can be alleviated – in this case, however, it is not a matter of *per se* bad actions, as they are referred to in the prohibition of theft at the level of *natural law* (*ius naturale*), but rather of an application of *human law* (*ius positivum*) that is expressed in concrete property ownership. Of course, means-end proportionality must be preserved here as well.<sup>6</sup> It becomes clear from this example that the end-to-end proportionality cannot be subject to evaluation by the acting parties, least of all by the potentially injured party, rather by the injuring party, who is the beneficiary of the action. Instead, this requires a neutral, superior point of view, which determines whether a good is to be regarded as absolute, i. e., removed from any consideration of ends, or as relative, i. e., open to a consideration of ends, and which additionally determines which consideration of ends can be justified and which cannot.<sup>7</sup> In this respect, the *principle of proportionality*, which is still to be discussed (but only if goods are weighed against goods, not if evils are weighed against goods), can also be regarded as an integral part of the principle of double effect.<sup>8</sup>

Now, as far as the principle of double effect is concerned, the interpretation which deals with absolute goods is appropriate. Thus, the life of a human being is an absolute good that may not be violated under any circumstances – not even on the basis of a good intention, if the normative logic underlying this argumentation would ever allow us to speak of good intentions when killing a human being (we saw, after all, that a good intention can refer solely to the defense of one's own life). Death or the acceleration of the occurrence of death, in other words, must not be intended under any circumstances. Thus, even a good intention cannot justify harm to an absolute good under any circumstances. Because in the case of self-defense the life of the aggressor is harmed or even ended (the killing of another person is always and under all circumstances reprehensible), the consistency of the moral theory is maintained by the fact that such harm, as already mentioned, may not be intended, but only accepted to achieve the intended goal, namely the preservation of one's own life. However, this absolute prohibition applies only with respect to actions that may result in

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<sup>6</sup> Another example in Thomas Aquinas is the death penalty, which provokes a societal evaluation, not only of the means in relation to the intended objective, but also the relevant goals themselves.

<sup>7</sup> This neutrality is also preserved where the person acts insofar as a legislator, in accordance with natural law in his concrete judgments. He does not, so to speak, arbitrarily deviate from human law in the name of natural law.

<sup>8</sup> It must be assumed that the determination of a good as absolute is itself absolute, i. e., the determination cannot vary depending on the situation when one and the same good is to be treated once as absolute and once as relative. In any case, an actor-neutral determination is required.

harm to other persons. Strictly speaking, in this case, one may not speak of an act of killing which is bad in itself (*per se*), but rather of an act of self-defense, which is good in itself (*per se*).<sup>9</sup>

At this point, a second moment of consideration arises, because it makes sense to reflect upon when it is necessary to apply the principle of double effect to medical ethical circumstances.<sup>10</sup> As a start, we identify cases in which two persons (or more) are involved, so that the advantages and disadvantages of a medical intervention relate to *different people* (this corresponds most closely to the original constellation envisaged by the principle of double effect). We cannot discuss in depth such scenarios here, which would have to be analyzed in more detail, as in the case of therapeutic abortion, for example, but we can use the original meaning of permissible self-defense as unfolded by Thomas Aquinas as an example for this. However, here too one could offer various plausible interpretations, depending on whether it is said that the medical intervention intends the death of the unborn or merely accepts it since it is obviously not a spontaneous reaction but a planned intervention.<sup>11</sup> It is unmistakable that the formula “not intended, only accepted” is not only theoretically consistent insofar as solely a good and not an evil may be intended, but also practically plausible as in the case of self-defense since it is a spontaneous reaction, not a planned action, which can be subjected to deliberative processes. Insofar as deliberative considerations can take place, they must use the means to achieve the goal as parsimoniously and as appropriately as possible.

This must be distinguished from cases in which the welfare of only *one person* is at stake and a benefit can only be ensured or assisted by also inflicting harm on that same person. It remains to be clarified whether the principle of double effect can be meaningfully applied to such cases as well. Authors who advocate this, as we shall see, noticeably interpret the principle of proportionality in terms of the principle of parsimony of means in order to avoid the idea that the patient might have to decide on the reasonability of ends by willing, i. e., intentionally seeking, not only the good to be achieved but also the evil that an action can (and, according to this restrictive interpretation may) “unintentionally” produce. It is, therefore, necessary to consider whether it makes sense to apply the doctrine of double effect to medical ethical contexts in which advantages and disadvantages are not distributed

<sup>9</sup> Cf. Scherer, *Die per se schlechte Handlung* (see fn. 2), 260.

<sup>10</sup> The principle of double effect was applied to medical cases only in late scholasticism and early modern times. Its classical form is reproduced for example in *Raus; Sterckx; Mortier*, doctrine of double effect (see fn. 5), 177–201, 180.

<sup>11</sup> One could choose the absurd interpretation that by an intervention only the reduction of the skull of the fetus is intended, but not the death of the fetus; cf. *Rau; Sterckx; Mortier*, doctrine of double effect (see fn. 5), 183: “In the Craniotomy Case, for example, one might say that the physician merely intends to reduce the size of the unborn child’s skull with the bad side-effect that the unborn child dies and the good side-effect that the mother survives.” There is an alternative reformulation that focuses not on the intention but on the reason, in order to make the action appear less arbitrary. Even if in the case of an abortion a certain goal of action is intended, the decisive factor is the reason for the action in question, for example: to save the life of the mother. According to other authors, it is a matter of establishing a certain situation that justifies an action that has a harmful effect, in this case saving the life of the mother. However, it is impossible to see why these interpretations should represent a fundamental difference from the attribution of an intention, since a reason for action alone does not constitute a justification, and the traditional justification of self-defence cannot also pertain to a situation.

among two (or more) persons but relate to a single person. This will be done using the example of palliative sedation. For in such a context it is initially unclear whether the effects of sedation are good or bad (except, of course, for the effect of pain relief). It should be noted that weighing the advantages and disadvantages arising from medical interventions is done in most cases without even discussing, let alone applying the principle of double effect. Therefore, it is necessary to justify how those cases, in which this principle is discussed or applied, differ from so-called “standard cases”.

### 3. Unclear Conditions

As a starting point we might propose the perhaps surprising insight that applying the principle of double effect to medical ethical contexts could open the door to a rather liberal conduct. One can always invoke a “good intention” and defend the “bad” consequence as merely accepted. We will come to this problem later. Daniel P. Sulmasy, in an attempt to ward off this interpretation, discusses the case of “parsimoniously-used direct sedation”<sup>12</sup>. The concept of direct sedation is introduced because it is to be distinguished from the concept of sedation that is aimed at the treatment of pain or symptoms and in this respect only indirectly causes a reduction of consciousness (at least according to the intention). This type of sedation, he argues, is not suitable as an example of a merely accepted side effect; it, therefore, also cannot be seen as a legitimate application of the principle of double effect because, on the one hand, we are dealing with a consciously chosen medical means and, on the other hand, the intended end is not to combat or alleviate pain or symptoms, but to suppress consciousness, i. e., to reduce or eliminate the perception of pain or symptoms. If this is the case and, in addition, it is assumed that the reduction of consciousness is an evil, such a conduct cannot be justified by the principle of double effect. We will defer the discussion of whether the diminution or extinction of consciousness can ever be good, but at this point, we share the intuition that it is usually an evil insofar as the autonomy of the person is impaired (temporarily or permanently).

In contrast, as stated, the principle of double effect would allow the treatment of pain and symptoms to be considered and justified as an intended goal, and the diminution or extinction of consciousness as merely an accepted effect. Specifically, it is argued that the practice of sedation can be justified by the principle of double effect when the aim is not a complete suppression, i. e., extinction of consciousness, but its reduction to a parsimonious degree just sufficient to treat pain or symptoms that cannot be controlled by other means. The point of this argument is that, in accordance with the principle of double effect, while the potential loss of consciousness as well as the potential acceleration of the onset of death is accepted, only a moderate and therefore parsimonious control of pain or symptoms, by means of the reduction of consciousness, is intended (while it is clear that the loss of con-

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<sup>12</sup> From Daniel P. Sulmasy, *The last low whispers* (see fn. 3), 233–263. He refers to Timothy E. Quill; Bernard Lo; Dan W. Brock; Alan Meisel, *Last-resort options for palliative sedation*, in: *Annals of Internal Medicine* 151 (2009) 421–424.

consciousness as well as the acceleration of the onset of death is not connected with this practice of sedation in a necessary but only in a contingent way). After all, the measured and therefore parsimonious use of appropriate means provides an objective, empirically-based reference in order to achieve the goal to alleviate pain and to control symptoms, while making medical intervention initially not dependent upon the subjective judgment of the patient (we will return to the determination of what should be considered suffering and how the overcoming of suffering should be measured), but subject to the expertise of the physician. Therefore, the conclusion could be drawn— since only as much of a means is used as is necessary to achieve a dissociation between consciousness and the pain or symptoms (and precisely not to aim at an extinction of consciousness or even an acceleration of the onset of death) – that such an action can be called proportionate, which corresponds to the principle of double effect.

But this very assessment is untenable for Sulmasy. The problem, in his view, is that an unclear concept of proportionality is being used. What is meant by this is not compatible with either means-end or end-end proportionality. Indeed, if it is stated that one intends only a sedation, but not an eradication of consciousness, one does not think about the proportionality of ends and thus about the balance between two effects (for example, pain and symptom treatment against "respiratory depression") but determines an appropriate means with regard to and intended end. More precisely, one compares the degree of the effect of the medical intervention to a continuum, ranging from the reduction of consciousness to its extinction, in order to determine the most parsimonious use of relevant means for the goal to be achieved.<sup>13</sup> More briefly stated, the situation isn't about two effects that are compared, but rather about different degrees of the same effect. Thus, the alleged "proportionality," it is concluded, has nothing to do with the principle of double effect. Therefore, appealing to this principle is entirely unsuitable to justify direct sedation. At most, this type of action can be justified by the principle of parsimony, which is the necessary but not the sufficient condition for legitimizing the practice of sedation. However, the argumentation presented by Sulmasy fails to recognize that the principle of parsimony – as already indicated – is essential for the principle of double effect, while the principle of proportionality remains beyond consideration in the case of an absolute good (and is applied in a party-neutral manner in the case of relative good, which is weighed against evils that are related towards other persons).

In addition, Sulmasy argues that palliative sedation, which doesn't lead to a reduction but to the eradication of consciousness and the acceleration of the onset of death, cannot be justified under any circumstances.<sup>14</sup> As an exception, he accepts only a case in which consciousness is so preoccupied, indeed overwhelmed – by pain or by comparable symptoms – that it can no longer perform any of its functions.<sup>15</sup> In this case, sedation leading to the

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<sup>13</sup> Cf. *Daniel P. Sulmasy*, Sedation (see fn. 4), 174 f.: "When sedation is the means of achieving the good effect, however, there is no double effect, even if one is careful about not giving too much drug."

<sup>14</sup> Cf. *ibid.*, 174 f.

<sup>15</sup> Cf. *ibid.*, 177: "To justify sedation to unconsciousness without violating any of the Canons of Therapy, the patient's consciousness would need to have been totally overwhelmed by the symptom, such that none of the humanly realizable goods subserved by consciousness could still be achieved. Under these circumstances, treatment would serve only to free the patient from the symptom, not to suppress any effective consciousness."

extinction of consciousness would be justifiable. The basis of this judgment is the understandable consideration that human consciousness represents a fundamental good insofar as it is a prerequisite for the creation of almost all other goods. It is also understandable that there must be good reasons for reducing or eliminating consciousness – as such measures deprive a person of her ability to pass judgment on her stage of being and of her capacity to evaluate herself or to provide information about she should be treated. So, if there are legitimate reasons for complete and continuous sedation, there are admittedly means to assert so-called extended autonomy needed. But what it means to say that such reasons must be “extremely serious” is left open by Sulmasy eventually. Also, the addendum that such considerations may only take place within an “extremely short” time span, i. e., at the very end of life, is not further substantiated, but rather simply assumed.<sup>16</sup> What becomes clear within this interpretation is, nevertheless, that the patient’s autonomy plays a subordinate role and therefore cannot be described as the “highest good.” To hint at the idea that not autonomy but God represents the highest good of man is not helpful because such a statement would have to clarify at the most basic level how the freedom of God should relate to the freedom of human beings.<sup>17</sup>

In addition, the condition under which sedation may be administered, especially if it eliminates consciousness, is that a person must not be prevented from fulfilling moral and religious duties. If this is not to be understood as meaning that a person is entitled to judge herself whether this condition applies to her, then the agent-neutral assessment can be derived that a patient’s consciousness must already be impaired to such an extent that the fulfillment of religious and moral duties is no longer conceivable, which would provide appropriate and justifiable grounds for deep and continuous sedation. An argument that regards moral obligations, for example in the form of family obligations, as being violated by continuous and deep sedation is not convincing, firstly because such obligations exist

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<sup>16</sup> Cf. *ibid.*, 177: “Consciousness is such a profound human good that it can only be sacrificed intentionally and permanently for an extremely grave reason in the setting of an extremely short remaining lifespan. Under such extreme conditions, sedation to unconsciousness can be viewed as having taken away something bad (pain), but without also sacrificing any of the goods achievable through continued consciousness. What I am suggesting is that directly intended sedation to unconsciousness could only be considered restorative, proportionate, and parsimonious if there is a physical symptom that has been refractory to all other forms of medical therapy, short sedation to unconsciousness (including the use of adjuvant therapies that themselves have substantial and synergistic sedation effects) and if this symptom is *so severe* that it has, in and of itself, totally consumed the patient’s consciousness.”

<sup>17</sup> Cf. *Douglas Farrow*, *Reckoning with the last enemy*, in: *Theoretical Medicine and bioethics* 39 (2018) 181–195: “It belongs to the Christian notion of human dignity to allow that a patient should have the freedom to accept or refuse care. It does not belong to it to allow that options such as permanent deep sedation or euthanasia are properly called ‘care.’ It belongs to the Christian notion of dignity to allow for autonomy. It does not belong to it to allow that autonomy is the soul’s highest good. Rather, God is the soul’s highest good. To acknowledge God as the highest good requires self-discipline on the part of patient and caregiver alike. The latter will not be able to recognize as rights what are sometimes called rights, or to dispense the mercies he is sometimes implored to dispense. For among these ‘rights’ or ‘mercies’ are things by their very nature closed to the good of the soul and, hence, intrinsically evil. All they can accomplish is to help send a soul to God in a state of mortal sin. Such is the result of regarding suffering rather than death as the last enemy.” The following statement is puzzling: “These words show the limits of the autonomy principle, which has its proper place in medical ethics but, pressed too far, is a dangerous illusion. What the person at the point of death needs to hear, or hear again, is the wonderful truth that he or she is not altogether autonomous but is invited to be altogether free.”

only in certain cases, especially in contractually regulated relationships, but not in general or, if they exist, can be voluntarily seized by the relatives. Secondly, if they exist, they cannot justify the obligation to suffer pain, at least in the last phase of a person's life, especially since a person's authority can be prolonged or substituted (especially by an advanced directive or a specific power of an attorney). The religiously motivated argument that the dying person can only prepare for the encounter with God while fully conscious is also not valid, because this preparation can be completed before the death of the person or before continuous and deep sedation (apart from the fact that it would only affect those persons who feel themselves committed in such a way). It is further argued that continued pain could give rise to "new sins." But it remains rather unclear what is meant by such an assessment. Above all, effective treatment of pain and symptoms by deep and lasting sedation would be a means of forestalling such sins, should they be induced thereby. All in all, the arguments mentioned do not justify a categorical obligation but merely remind us that serious reasons must be given for continuous and deep sedation – which is so far undisputed.

Now, by this argumentation, the legitimacy of a graduated judgment of action is conceded. Strictly speaking, prohibiting the erasing of consciousness by palliative sedation contradicts the statement that "parsimoniously-used sedation" can be justified in cases in which consciousness is, to a certain extent, overwhelmed by pain or symptoms since even such parsimoniously-used sedation can lead to extinguished consciousness when it is the only way to achieve pain or symptom control.<sup>18</sup> From the point of view of the effects or the effectiveness of sedation, there can be no categorical difference but only a gradual difference between a form of sedation, which leads to a reduction in consciousness, and a form of sedation that leads to the elimination of consciousness. This holds true even when sedation may only be used to the extent necessary to alleviate pain and to control symptoms. Of course, if so desired, one can make a categorical distinction between the reduction and the extinction of consciousness. Here, however, we are then not dealing with a judgment on actions – in the light of the pain or symptom control to be performed – but with a judgment on the expected performance of consciousness, concerning especially the status of a patient's capacity for autonomy.<sup>19</sup> What is the rationale for this position?

The relief of suffering itself, Sulmasy continues surprisingly, is never the goal of medicine. Rather, as he points out, medicine strives for healing. However, when pursuing the elimination of consciousness, healing is not possible. (This logic, as mentioned, unfortunately does not apply in cases when consciousness is already overwhelmed by suffering). Thus, with regard to the goal of healing, any state would be better than a stage in which

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<sup>18</sup> Cf. *Daniel P. Sulmasy*, *The last low whispers* (see fn. 3), 233–263, here 233: "It is concluded that, if one is opposed to euthanasia and assisted suicide, double-effect sedation can frequently be ethically justified, that parsimonious direct sedation can be ethically justified only in extremely rare circumstances in which symptoms have already completely consumed the patient's consciousness, and that sedation to unconsciousness and death is never justifiable."

<sup>19</sup> A permanent reduction or extinction of consciousness and thus of the basis for conscious decision-making and action (rational agency) is to be distinguished, for example, from anaesthesia during an operation and represents a particularly deep intervention in a patient's capacity for autonomy, which is why stricter conditions should be formulated for this step from an ethical point of view.



consciousness is extinguished. Therefore, the extinction of consciousness cannot be a legitimate goal of medical conduct. Suppose, Sulmasy adds, that one was to insist that the intention in treating a dying person with a sedative drug is alleviating suffering, and suppose that this could be justified by the principle of double effect. Under such conditions, sedation would have to be regarded as an intended means for achieving this goal. If this were so, then a means has admittedly been chosen that is in itself neither good nor neutral but bad for the human being, if it diminishes consciousness and, even more so, if it extinguishes consciousness or even accelerates the onset of death, such that one of the stated conditions of the principle of double effect would not be fulfilled. Here Sulmasy simply presupposes and does not further justify why the alleviation of suffering should not be the goal of medicine and why the diminution or extinction of consciousness or the hastening of the onset of death should be neither a good nor an indifferent or neutral condition. Thus, if the alleviation of suffering is regarded as a legitimate goal of medical action, sedation must be conceived as the consciously aimed or intended means of action.

#### 4. An example of the application of palliative sedation

In order to critically examine the ethically justifiable use of the principle of double effect in the case of palliative sedation or the limitations of such use, we, as a first summary, can systematize the relevant effects of palliative sedation as follows: (1) pain relief (although it must be left open as to what is considered pain or who is to judge what can be considered pain), (2) diminution or elimination of consciousness, if applicable, and (3) acceleration of the onset of death, if applicable. (1) can be considered a good, (2) either a good or an evil, (3) neither a good nor an evil. For (3) this is true, provided that, compared to (2), no further good can be achieved and then, of course, no additional evil produced, at least if consciousness is continuously eliminated, and provided that no further evil is produced in that the life-shortening effect of sedation occurs against the will of the person in question. In addition, let us consider the following facts: (1) Empirically, it is controversial whether the correct, i. e., – measured against the end to be achieved – parsimonious use of a sedative measure can also have a life-shortening effect; for the sake of ethical argument, we simply assume that it can have this outcome.<sup>20</sup> (2) Empirically, it will also have to remain uncertain whether the life-shortening effect, whether it truly occurs or is only an assessment stem-

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<sup>20</sup> The question whether palliative sedation has a life-shortening effect is controversial and can only be answered based on empirical research. We conduct the discussion as if this effect existed, in order to achieve an ethical evaluation of palliative sedation with a life-shortening effect under this hypothetical condition. See, for example, *Antony Takla; Julian Savulescu; Dominic J. C. Wilkinson; Jaideep J. Pandit*, General anaesthesia in end-of-life care: extending the indications for anaesthesia beyond surgery, in *Anaesthesia* 76 (2021) 1308–1315; *Nigel Sykes; Andrew Thorns*, The use of opioids and sedatives at the end of life, in: *Lancet Oncology* 4 (2003) 312–318; *Guido Miccinesi; Judit A. C. Ritjens; Luc Deliens; Eugenio Paci; Beorg Bosshard; Tore Nilstun; Michael Norup; Gerrit van der Wal*, Continuous deep sedation: physicians' experiences in six European countries, in: *Journal of Pain and Symptom Management* 31 (2006) 122–129, here 125. The methodological difficulty lies in isolating a causal link between sedation and life shortening. Nevertheless, it is plausible that as long as this uncertainty exists, a medical intervention must be justified accordingly.

ming from the imagination of the physician concerned, is intended or not. We simply assume that it does not have this result. (3) Finally, it is unclear for which of the parties involved – physicians, but above all patients and relatives, – an accelerated onset of death represents a good or an evil, especially since there are conceivable constellations in which the assessment of this situation is truly controversial.

#### 4.1 The Principle of Parsimony and the Principle of Proportionality

Let us revisit the principles mentioned above. In palliative sedation, the principle of parsimony (therapeutic parsimony)<sup>21</sup> initially refers not to the balance of two effects, but to the degree of a single sedation effect. Thus, it is two effects that are balanced against each other, for example, pain relief and diminution of consciousness; rather, the aim is not to sedate more than is necessary for pain relief. Of course, the principle of parsimony also aims at not impairing consciousness for the purpose of symptom or pain relief more than is necessary for this purpose.<sup>22</sup> As long as no side effects result from pain therapy, the principle of parsimony is sufficient in itself. After all, its purpose is precisely to avoid undesirable side effects. As soon as undesirable side effects are to be expected, they must also be justified, i. e., weighed against desirable effects. This is where the *principle of proportionality* enters the picture as a secondary rule. Pain relief and diminution of consciousness, for example, must be weighed against each other. Of course, a physician is dependent on the patient's perception (*Wahrnehmung*) in estimating the pain-relieving effect – it follows consistently from this that only the patient can ultimately determine what counts as pain or suffering.<sup>23</sup> But we distinguish such an assessment – of the pain- or symptom-relieving effect – from the balancing of the possible consequences of a medical indication, which we call value perception (*Wertnehmung*) and which belongs to the (informed) patient alone. This may take the form, for instance, of a patient's willingness to endure pain in order to remain in full possession of his or her consciousness. The distinction between the two principles only makes sense if they are applied, on the one hand, to the person of the physician (*principle of parsimony*) and, on the other hand, to the person of the patient (*principle of proportionality*) – for this purpose we resort to the model of “shared decision-making.”<sup>24</sup> As already established in the use of terms, a distinction is made between “means-end proportionality” and “end-end proportionality.” So-called “Means-end proportionality” is about finding the right means for the realization of a certain end. This issue, as

<sup>21</sup> Cf. Edmund D. Pellegrino; David C., Thomasma, *A Philosophical Basis of Medical Practice: Towards a Philosophy and Ethic of the Healing Professions*, New York 1981, 139.

<sup>22</sup> Cf. Daniel P. Sulmasy, Sedation (see fn. 4), 171–180; similarly, Farr A. Curlin, Palliative sedation: clinical context and ethical questions, in: *Theoretical and Bioethics* 39 (2018) 197–209.

<sup>23</sup> Cf. Claudia Bozarro, Der Leidensbegriff im medizinischen Kontext. Ein Problemaufriss am Beispiel der tiefen palliativen Sedierung am Lebensende, in: *Ethik in der Medizin* 27 (2015) 93–106, here 97: Suffering is a subjective experience that can only be grasped to a limited extent intersubjectively, let alone be verified.

<sup>24</sup> To distinguish between the physician's assessment of consequences and the evaluation of them from the patient's perspective, cf. Christof Breitsameter, Medical decision making (see fn. 3), 349–352. It is clear that information and value considerations pervade practice: The physician is informed by the patient who talks about his or her values, and value considerations will always play into the physician's selection of information. In this respect, the demarcation line between knowledge and value must remain fluid.

already emphasized, can be related to the principle of parsimony, and its application is the responsibility of the physician. End-end proportionality, on the other hand, is about weighing different effects in the use of a particular means. This situation can be related to the principle of proportionality, its application is incumbent upon the patient.

The principle of double effect can neither satisfy the principle of parsimony nor the principle of proportionality if it applies that the assessment of pain or suffering as well as the weighing of desired and undesired effects can be made by the patient alone. Once again, it can be seen that the principle of double effect originally pertained to different persons, which is why an agent-neutral point of view could be justified. If one follows the model of “shared decision-making,” the “means-end proportionality” is subject to the assessment of possible consequences (*Folgenabschätzung*) by the physician and the “end-end proportionality” to the evaluation of these consequences (*Folgenbewertung*) by the patient. In this context, it is deliberative to emphasize the impairment of consciousness over other side effects, especially since it cannot be ruled out that this reduction in consciousness is among the desired effects. The judgment as to whether the reduction or even extinction of consciousness should be the goal or means of medical intervention can (as, incidentally, also in the case of pain relief) be the sole responsibility of the well-informed patient, as can, of course, weighing the degree of reduction of consciousness against the relief of pain. However, as also noted above, consciousness is the basis for autonomous value decisions. Therefore, any decision to relinquish this is of notable importance, especially if the loss of consciousness is to be made irreversible at the patient’s request. Once this loss has occurred, an effect that hastens death admittedly remains ethically meaningless, no further harm can come to the patient.

From a physician’s point of view, sedation may only extinguish consciousness if the pain or symptoms are so severe that consciousness can no longer perform any of its functions. From the patient’s point of view, any well-thought-out reason is a reason for sedation of any kind. Unlike the medical indication, the described condition does not have to have taken place; it can be anticipated and still be considered a reason for any form of sedation. The assertion that sedation that eliminates consciousness and hastens the onset of death can never be ethically justified, (we have mentioned the permitted exception) ignores the subjective perspective of the patient, which would be irrelevant and would be sacrificed to the objective assessment of the physician. Thus, if the issue is to sedate continuously and deeply, two aspects have to be taken into consideration: On the one hand, the medical one, which declares a considerable burden of symptoms to be a prerequisite for sedation; on the other hand, an individual one that, with every additional deepening intervention, raises the demands on the patient’s capacity for autonomy. Such a “sliding-scale strategy” would stipulate, for example, that in addition to proving a person’s ability to make autonomous decisions, the coherence of a decision with a patient’s biography or values must be demonstrated.<sup>25</sup> Here, one could speak of a rationality bound to rules, or also of a *value-based rationality*.

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<sup>25</sup> Cf. *Eva C. Winkler*, Ist ein Therapieverzicht gegen den Willen des Patienten ethisch begründbar?, in: *Ethik in der Medizin* 22 (2010) 89–102, 97: “Not all moments of a decision are rational, but the demonstration of a decision’s coherence with one’s life plans and basic beliefs has justificatory character. Initially, the assessment of this

Normatively, this has two consequences for medical intervention: On the one hand, the *principle of parsimony* applies, insofar as consciousness should only be reduced to the extent required to combat pain or to control symptoms; on the other hand, the *principle of proportionality* applies, insofar as this proportion is to be determined, i. e., it must be clarified how much consciousness should be maintained, even if pain or symptoms will remain burdensome, and it must be clarified what is regarded as pain as well.

#### 4.2 The principle of double effect

The tenet that not only the intended but also the known consequences of an action must be answered for makes the principle of double effect, in its classical form, obsolete. Because if there is a medication that relieves pain without impairing consciousness and medication that relieves pain and impairs consciousness to a greater or lesser extent and more or less continuously, a physician must (be able to) distinguish between the expected effects, which is why she has to be aware of the consequences and is therefore also responsible for them. Whether the consequences are intended or not is irrelevant. Therefore, it is a well-established principle in modern legal contexts to use not only what is intended but also what is known, i. e., what is accepted, when evaluating actions. Moreover, if one followed the doctrine of double effect, a serious differentiation of ethical evaluation would be built on a distinction that is difficult to verify intersubjectively.<sup>26</sup> Consequently, the term “indirect euthanasia,” which has become customary, must also be abandoned.

### 5. Distinction from ‘death on request’

What distinguishes the induction of continuous and deep sedation, through which consciousness is eliminated *and* the onset of death hastened, from so-called ‘death on request’? First, one could state that a person ceases to exist as soon as, and as long as, consciousness is erased, regardless of the acceleration of the onset of death. But in addition to this common view, there are also differences: On the one hand, sedation can be withdrawn, i. e., it is not irreversible, and the acceleration of the onset of death can extend over a longer period of time (slow euthanasia)<sup>27</sup> than is usually the case with death on request. This, however, is only a gradual, not a categorical difference. On the other hand, there may be a moral difference for a person whether he or she is sedated in this way or dies on her own request, even if this difference does not exist on closer analysis or is based solely on the intention

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coherence will be the patient’s alone. However, by giving reasons for a chosen option, he or she encounters another on a terrain where both want to agree on the correct reasons for a decision. This is not to say that the physician should follow the patient’s desire for maximum therapy only if he can understand it or if the patient’s ideas are consistent with his own, but the weaker the justification of a therapy by medical reasons, the higher the requirements for justification by the patient’s will.”

<sup>26</sup> Cf. Timothy E. Quill; Rebecca Dresser; Dan W. Brock, The Rule of Double Effect – A Critique of Its Role in End-of-Life Decision Making, in: *The New England Journal of Medicine* 337 (1997) 1768–1771.

<sup>27</sup> Cf. Charles Douglas; Ian Kerridge; Rachel Ankeny, Managing intentions: the end-of-life administration of analgesics and sedatives, and the possibility of slow euthanasia, in: *Bioethics* 22 (2008) 388–396; J. Andrew Billings; Susan D. Block, Slow euthanasia, in: *Journal of Palliative Care* 12 (1996) 21–30.

of the person concerned. If a person fears that the elimination of his or her consciousness will not be comprehensive and that he or she may continue to feel pain, he or she might even prefer death (on request) to sedation; if she feels morally bound in the way described, she might conversely prefer sedation over death. Therefore, sedation cannot be justified simply by saying that, compared to death on request, it is a lesser evil (apart from the fact that it may, though need not, be a good for a patient). Sedation can, in effect, hasten the onset of death and viewed in this light, to co-cause it (if the disease in question is also considered a cause of death).<sup>28</sup>

Neither is it a convincing suggestion that palliative sedation, even if it has a life-shortening effect, is a measure impending in the dying process or imminent right before death: this can also apply to death on request so that one could at most attempt to establish a point in time for both measures from which they are considered legitimate. What is then crucial is to what kind of normative significance such a determination must refer. If the process of dying and the medical intervention were indistinguishable, there would be no need for the medical intervention which thus leads to a shortening of life.

The principle of double effect, it can be concluded, is not suitable for distinguishing palliative sedation (which brings with it an acceleration of the dying process) from so-called death on request in an ethically significant way.<sup>29</sup> More precisely: From an ethical point of view, sedation does not represent a significant difference from death on request if it is associated with a lasting extinction of consciousness and an acceleration of the onset of death, and it can be assumed that no additional harm will occur for the patient in the case of death on request.

## 6. Conclusions

Three questions remain to be considered: (1) How does the principle of proportionality relate to the principle of parsimony? The principle of parsimony is sufficient for measures of symptom or pain relief that result in an impairment of consciousness undesirable by the patient, whereby the application of the principle is up to the physician. The principle of parsimony is not sufficient for cases in which the reduction or elimination of consciousness is desired. Here the principle of proportionality must be added, the application of which is the sole responsibility of any well-informed patient. The application of the principle of

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<sup>28</sup> *Kasper Raus et al.*, Continuous sedation until death: the everyday moral reasoning of physicians, nurses and family caregivers in the UK, The Netherlands and Belgium, in: *BMC Medical Ethics* 15 (2014), 14, for example, state the difference between “continuous sedation until death” and “euthanasia”: “Some commentators argue that CS (continuous sedation until death) causes death and often amounts to ‘slow euthanasia’.” Here, it would be correct to speak of a “co-cause” because the disease is another cause and sedation does not cause death or, at most, is a cause of hastening death. And continuing, “Others argue that even if CS does not hasten death, it causes patients to permanently lose the capacity to communicate, and may thus amount to an imposition of social death of the patient.”

<sup>29</sup> In this, I argue differently than, for example, *Thomas A. Cavanaugh*, Proportionate palliative sedation and the giving of a deadly drug: the conundrum, in: *Theoretical Medicine and Bioethics* 39 (2018) 221–231: “Hence, in PPS the patient’s death is voluntary but not intended, while in PAS and euthanasia it is voluntary and intended.”

proportionality would not be the patient's task alone if there were generally accepted criteria for reasons that are right or wrong. In other words, there would be a need for a generally shared and specific notion of what a good life consists of. However, insofar as we will encounter differing views between doctor and patient or between one patient and another, it is not possible to really determine a shared concept of what a good life consists of. (2) When we observe these principles, is there still a need for the principle of double effect? Or to put it differently: Are parsimony and proportionality sufficient as principles? The principle of double effect is indeed not only unsuitable, as shown above, but also dispensable if we can confirm the rule that all known side effects must also be accounted for. Since this is followed in the principle of parsimony (in avoiding side effects) and in the principle of proportionality (in weighing effects and side effects), the principle of double effect can be dispensed with. Moreover, the principle of double effect fails when the extinction of consciousness is considered as a means of pain relief (because the means for a good objective may not be bad, and the reduction or extinction of a person's consciousness cannot be a good means), as well as when the extinction of consciousness is considered to be the very end of an action. At most, the diminution or extinction of consciousness can be considered an unintended consequence of an action that is intended to relieve pain. If pain relief were generally declared to be the end of medical action, this could in every case be achieved by a sedative measure that extinguishes consciousness. Two reasons count against this: First, on the side of medical indication, one will have to specify the ends of medical actions, which can be done with the help of *instrumental rationality* (means-end proportionality) or the principle of parsimony. On the other hand, and this is revealed by empirical research, it stands that the goal of pain control must be regularly balanced with the goal of maintaining the patient's consciousness as far as possible, which can only be done with the help of *prudential rationality* (means-end proportionality) or the principle of proportionality and therefore, as mentioned, only with consideration of the patient's will. Where wakefulness or awareness promises no gain in the quality of life, it is possible to go beyond the medical indication and thus beyond the principle of parsimony. (3) Does only physical or mental pain legitimize treatment that leads to the extinction of consciousness for the purpose of combating suffering? Even existential and spiritual pain can be grounds for palliative sedation even if it reduces or permanently erases consciousness or accelerates the dying process.<sup>30</sup> This follows from the prominent importance attached to the individual indication – especially since, in this case, undesirable side effects play no role. It would be arbitrary in the case of mental pain not to permit sedation that extinguishes consciousness, i. e., to permit only those forms of sedation that result in a diminution of consciousness (however strong this may be).<sup>31</sup> It would additionally be arbitrary to treat mental pain fundamentally differently from physical suffering. At best, it is the responsibility of medicine

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<sup>30</sup> Cf. *Paul Rousseau*, Existential suffering and palliative sedation: A brief commentary with a proposal for clinical guidelines, in: *American Journal of Hospice and Palliative Medicine* 18 (2001) 151–153.

<sup>31</sup> As with *Daniel P. Sulmasy*, The last low whispers (see fn. 3), 233–263. He argues here, for example: “If one would not prescribe a barbiturate-induced coma for despair or existential angst outside of a terminal context, why would such measures suddenly be indicated when a patient is dying?” Here, the determination of a “terminal context” is declared to be an evaluative assumption without further substantiation. Likewise, it is merely asserted,

to generate evidence for the occurrence of physical as well as mental pain, meaning that a valid individual indication would be inconceivable without a valid medical indication.

The old principle of double effect has been applied in a new field in recent decades, namely that of so-called palliative sedation. The article highlights the difficulties associated with this attempted transfer. There are substantial reasons to no longer refer to the principle of double effect in this medical context. The term 'indirect euthanasia', which presupposes the applicability of the above-mentioned principle, should also be abandoned. Consistently, not only physical suffering but also psychological, existential, and spiritual suffering can in theory be considered as ethically legitimate reasons for permanent and deep sedation, even if such measures hasten the patient's death.

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but not substantiated: "The suffering of despair can be greater than that associated with pain, but one's intervention to assist the suffering person must be proportioned to (i. e., must fit) the problem. Sedation does not fit the problem of agent-narrative suffering."