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Self-Experiment Rebooted. Historical and Ethical notes

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ABSTRACT

A case of ethics and media

In November 2024, the publication of a scientific paper concerning the self-administration of a self-prescribed therapy provoked a global uproar. This article examines the relevance of the case within the longstanding tradition of self-experimentation in medicine, as it was presented to the press, while arguing that it more accurately reflects the more recent phenomenon of experimental self-therapy, typically pursued by patients outside regulatory frameworks. Although the case raises new ethical questions regarding contemporary medical practice, it also demonstrates that the critical methodological issues which contributed to the decline of self-experimentation persist. Furthermore, advances in scientific research and the rise of personalized medicine may, in the future, bring renewed attention to such practices. The article also illustrates how a mythologized interpretation of medical history—particularly regarding the 'heroic' cases of self-experimentation—can distort the debate. Finally, it raises several questions concerning the publication practices within the medical-scientific field and the dissemination of medical information in the general press.

Keywords: Self-experimentation - Self-therapy - Publication practices - Personalized medicine

A case of self-therapy: is history cyclical?

In 2020, the Croatian virologist Beata Halassy underwent an oncolytic virus therapy (OVT) protocol she herself had developed based on her own bibliographic research to treat her breast cancer. Convinced of its therapeutic benefit, Halassy described her experience in a scientific paper[1] presented as a case report, explicitly referring to it as self-experimentation. The paper appeared in August 2024. In November of that year, the online general-interest journal *Nature News*[2] reported on the case, thereby bringing it into the public sphere. This publication has since become the focal point of a complex array of ethical and philosophical considerations (e.g. autonomy vs. paternalism, legitimacy of self-therapy), often–whether legitimately or not–evoking references to the historical tradition of self-experimentation.

In this paper, paragraphs 1-3 will focus on the argument put forward by Halassy and by the paper she defined as an "encouraging example". Paragraphs 4 and 5 will show how problematic these two papers are, drawing on the literature on history and ethics of self-experiment, and sum up the argument, highlighting the need for a thorough ethical analysis of the contemporary scenarios for self-experiment in life sciences.

1. The scientific paper

The scientific article at the center of this discussion, authored by nine scientists (with Beata Halassy listed last), was published in open-access format by the journal *Vaccines* on August 23, 2024[3]. It details a therapeutic protocol that Halassy–an active researcher at the University of Zagreb (with 76 publications indexed in Scopus and an h-index of 19)–developed for her own use, drawing upon her expertise and a comprehensive review of the medical literature.

At the time she initiated the virus-based therapy, Halassy was 49 years old and experiencing a second recurrence of invasive breast cancer following a total mastectomy and the corresponding chemotherapy regimens.

In the article, Halassy reports undergoing the experimental therapy for two months without significant adverse effects. Observing a reduction in tumor mass and its detachment from previously infiltrated surrounding tissues, she subsequently underwent surgical removal of the tumor. During this two-month period, she was under the supervision of an oncology specialist. After surgery, she adhered to the standard clinical protocol, which included administration of the monoclonal antibody trastuzumab. Four years later, at the time of publication, she reports being in good health.

The authors posit a causal relationship between the self-administered therapy and the reduction in tumor mass. Histopathological examination of the excised specimen revealed infiltration by lymphocytes and macrophages, consistent with a localized viral infection. The article concludes that this case provides encouraging evidence for the potential use of oncolytic virotherapy as a neoadjuvant treatment (i.e., preceding surgical intervention).

Oncolytic Virus Therapy (OVT)

Oncolytic virus therapy (OVT) is an experimental treatment modality targeting a limited range of cancer types. It involves the use of genetically modified oncolytic viruses, which inherently display a greater affinity for infecting tumor cells than healthy cells. Although the conceptual groundwork for OVT dates back to the early 20th century–when certain viral vaccines were observed to potentially induce tumor regression–substantive research in this domain only began in the 1980s[4]. Today, OVT remains a niche area of oncology research, though some investigators consider it to hold promise[5].

At present, only one OVT-based therapy has been approved by the United States Food and Drug Administration (FDA)[6]. This therapy employs a herpesvirus vector for the treatment of inoperable metastatic melanoma. Beyond this single FDA-approved agent, three additional oncolytic virus therapies have been authorized in a small number of other countries[7], although they are seldom utilized in clinical practice.

Notably, Latvia has exclusively approved and patented a therapy known as Rigvir, which is based on the ECHO-7 virus. This agent is marketed online for off-label use against various oncological diseases, and a purported tumor-preventive dietary supplement is also sold under the same name[8]. Rigvir therapy, however, has not undergone rigorous clinical evaluation and is not regarded as reliable by the broader medical-scientific community, which has repeatedly cautioned both healthcare institutions and the general public against its use[9].

Ethical References

Rather than presenting the approval of an Institutional Review Board (IRB)–customarily required for biomedical research publications–the article states that, as a case of self-experimentation, such approval was deemed unnecessary. This claim met the editorial board's requirements despite the journal's own author guidelines[10]. It is supported by three bibliographic references: one by Brian P. Hanley and colleagues (to be discussed further), another published in *Vaccines* describing self-experiments involving anti-Covid vaccines[11], and a third article by the same group (in a different journal)[12] that was later retracted[13]. All three references describe self-experiments carried out without IRB oversight. In lieu of an IRB statement, the article explains: "The study was feasible solely due to the unique circumstances in which the patient was also a virology expert. The patient was fully aware of her disease and the available treatments and, as a scientist in the field of virology, recognized the potential of oncolytic virotherapy. After experiencing two recurrences of the same tumor, she wished to try an innovative approach in a scientifically valid manner[14]." At the conclusion of the paper, it is noted that Halassy has initiated a consulting relationship with a biotech company (Vyriad) and has filed a patent application.

The Publishing Journal

Vaccines is an open-access journal published by the Swiss firm MDPI, which–like many open-access venues–charges a publication fee. In this instance, the fee for an accepted manuscript (following peer review) is 2,700 Swiss francs[15].

Vaccines became embroiled in controversy in August 2021, when it published (and subsequently retracted) an article[16] promoted by anti-vaccine activists and authored by three proponents of alternative medicine, which alleged unsubstantiated risks associated with Covid-19 vaccination. That article contained multiple errors and had not undergone peer review; following its publication, much of the journal's editorial board resigned[17]. MDPI, a publisher specializing in open access and overseeing 433 scientific journals, has also faced accusations of predatory publishing practices[18].

The scientific paper becomes news

The first general-interest media outlet to report on the publication of the scientific paper was the online journal *Nature News*[19], which conducted an interview with Beata Halassy. Although the paper had been published earlier, it was not until its coverage by *Nature News*–released on November 8, 2024, for reasons that remain unclear–that the story garnered widespread media attention, thereby prompting the present investigation.

The content of the *Nature News* interview is pivotal to the objectives of this article. In that interview, Halassy states that she encountered considerable difficulties in publishing her scientific paper, having submitted it to approximately a dozen journals before succeeding. She attributes most of the rejections to ethical concerns related to self-experimentation.

To address these concerns, *Nature News* consulted Jacob S. Sherkow, a professor of law at the University of Illinois and an expert in biosciences and bioethics. Sherkow opines that publishing the paper might lead other cancer patients to emulate Halassy's approach, potentially abandoning conventional therapies in favor of comparable treatments available online–an outcome he regards as a serious mistake.

Halassy, for her part, counters that carrying out OVT-based self-therapy requires substantial virological expertise, rendering it unlikely that others could replicate her procedure. She also emphasizes that publishing the paper secured new funding for further study of OVT. In subsequent interviews, Halassy carefully notes that adequate clinical trials remain necessary and that her own case should be viewed as unique and not replicated outside of controlled settings[20].

Another notable aspect of the *Nature News* interview involves the protocol's design. Halassy explains that she selected two viral vectors with which she was well-acquainted in her capacity as a virologist. Although not a specialist in oncolytic virotherapy, she maintains that these two viruses were chosen for their perceived safety. Stephen Russell, an OVT expert contacted by the same journalist and the proprietor of a bio-

tech company focusing on oncolytic virotherapy, points out that such arbitrariness undermines the possibility of deriving generalizable conclusions. He says: "Really, the novelty here is, she did it to herself with a virus that she grew in her own lab."
A third point of interest emerges from an article cited both in the references of Halassy's paper (including its justification for not seeking institutional review board approval) and in the *Nature News* coverage (here, alongside Halassy's paper). Regarding her challenges in publishing and her determination to disseminate her case, Halassy explains that she found strong motivation in that article[21]: authored by Brian P. Hanley and two other biotechnologists, the piece merits separate discussion. It is there that references to historical self-experimentation cases from the previous century appear, along with an ethical argument in favor of self-experimentation–an argument that Halassy evidently found encouraging when deciding to publish her own account.

2. An 'encouraging' example

The article cited by Halassy as an inspirational source was published in *Rejuvenation Research* in February 2019. The primary author is Brian P. Hanley, a Californian microbiologist who, in 2017, garnered media attention as "the first transgenic scientist in history"[22] for allegedly subjecting himself to an innovative gene therapy aimed at life extension. Born in 1957, Hanley has fourteen publications indexed in Scopus–including articles, reviews, and letters–with three contributions appearing in *Rejuvenation Research*. His current affiliation is with Butterfly Science, a biotechnology company he founded (its website being last updated in 2019), and his Scopus h-index is reported as 6.
The second author is William Bains, a biochemist, technologist, and innovator with an extensive record of establishing start-ups, consulting, and founding medical journals. In the article, he declares his affiliation with Rufus Scientific Ltd, a start-up he established, and he concurrently holds positions at the Massachusetts Institute of Technology (Department of Earth, Atmospheric, and Planetary Sciences) and at Cardiff University (School of Physics and Astronomy). His h-index, predominantly reflecting his publications in biochemistry and astrobiology related to the Venusian environment, is 31. In 2007, Bains published an article[23] in *Medical Hypotheses* entitled "Truly personalised medicine: self-experimentation in medical discovery".
Medical Hypotheses is a controversial journal, established explicitly without formal peer review mechanisms, with the express purpose of disseminating marginal hypotheses in the medical field. In 2009, two years subsequent to Bains' publication, the journal was involved in a significant controversy for publishing articles by HIV–AIDS denialists[24]. The controversy did not lead to a change in the direction of the editorial line[25].
The third author is the eminent American geneticist George Church of Harvard Medical School, Boston, whose scholarly influence is reflected in an h-index of 169.

Church is also the co-founder of a company dedicated to pursuing indefinite life extension, one of approximately fifty start-ups he has helped establish. Notably, Church has co-authored papers with as many as 3,942 collaborators.

The article has accrued 25 citations in Scopus, including one by Halassy herself, and has been referenced in journals covering historical analyses, bioethics, and alternative medicine. Among these citations is a 2021 publication[26]–again authored by Hanley et al. in conjunction with another co-author–in which favorable outcomes of Hanley's self-experimentation are reported; this work was also published in *Rejuvenation Research*. Consequently, it cannot be asserted that this article has exerted a substantial impact on the scientific literature or significantly advanced the ethical debate surrounding self-experimentation.

It is also pertinent to note that in 2019, Clarivate classified *Rejuvenation Research* among the biomedical journals with a high self-citation rate, leading to its temporary suspension from the Journal Citation Reports[27]; however, the journal was re-indexed in June 2021.

The article purports to examine self-experimentation from historical and philosophical perspectives, with the aim of demonstrating that ethical barriers to its practice should not be insurmountable. To bolster this thesis, the authors present data derived from a survey administered to various ethics committees and to a sample of scientists affiliated with prominent scientific societies.

Historical Citations and Statistics

The article by Hanley et al. begins by asserting that self-experimentation, despite being considered unethical and scientifically ineffective, is still widely practiced but kept secret due to fear of academic ostracism. It briefly cites the 20th-century cases of Barry Marshall and Werner Forssmann, who made two fundamental discoveries, awarded with the Nobel Prize, through self-experimentation, but were allegedly hindered by colleagues and thus had to operate covertly. This narrative, as will be discussed later, is not entirely accurate.

Following the brief historical references, the article refers to a sort of census conducted by cardiologist Allen B. Weisse in 2012[28]. Weisse had gathered information on 465 documented self-experiments over the previous two centuries and inferred rather arbitrary statistics on the periods of greatest expansion of the practice, the deaths he recorded (eight), and Nobel Prizes.

Hanley et al. add to Weisse's list a couple of famous recent cases, such as that of neuroscientist Russell Poldrack, who underwent a functional magnetic resonance imaging (fMRI) of the brain (which is entirely harmless), and that of geneticist Michael Snyder, who measured some vital parameters on himself. Among the recent cases, the self-gene therapy of the first author of the article itself is also mentioned, but without further elaboration.

Subsequently, Hanley et al. report the results of a survey they conducted in the Americas. A questionnaire was emailed to 203 ethical committees: 37 responded, and 25 among them explicitly reported the absence of internal regulations for self-experimentation. Considering this a good response rate, the authors claim that two-thirds of the scientific committees in the Americas do not have a policy on self-experimentation. The authors also circulated a survey among scientists, in order to assess the status of self-experimenting practices. Only 52 (out of 1072) replied, and 26 admitted to at least one self-experiment. Only 6 of them reported to have reached an ethical committee before conducting the self-experiment. According to the authors, the very low response rate was due to spam filters in e-mail systems.

Ethical Argument

The survey is followed by the so-called "ethical analysis". Hanley et al. mention the Nuremberg Code as the only international medical regulation that explicitly addresses self-experimentation, in article 5.

Subsequently, they discuss the potential benefits of a self-experiment, arguing that even an experiment on a single subject has high informational power. They briefly mention historical cases (Pasteur and the rabies vaccine tested on a single child among others), and the "reproducibility crisis in biomedical sciences" to argue that a study on a single subject may help in validating observations in animal model studies before moving to a large-scale study. The argument is supported by reference to old journalistic works and generic phrases such as "the value for many outweighs the discomfort or risk to a single person". The treatment is not entirely exhaustive and appears to be rather unsatisfactory.

In the conclusion, attention is drawn to the request for greater attention to the topic by ethics committees: "...it might be sensible for a self-experimenter with or without ethics committee approval to have a simplified procedure for notifying clinical trial regulatory agencies, such as the FDA and the European Commission...". Finally, in the Transparency Declaration, they write: "The authors have conducted experiments on themselves during their careers. The lead author has conducted an independent experiment with the intent to submit the data to the FDA".

3. Issues and Problems in this Case

Beyond the clinical case, what is primarily required is an ethical reflection on the legitimacy of experimental self-therapy itself—whether or not it is explicitly framed, in the intentions or in the declarations of the researcher, as self-experimentation. The Halassy case opens up a wide range of questions and reflections that will be addressed in this section, from the status of experimental self-therapy in relation to traditional notions of self-experimentation, to the broader implications for medical ethics and regulatory over-

sight. Closely connected to this is the equally crucial issue of the legitimacy of scientific communication: not only the publication of the article in *Vaccines* by the research group, but also its subsequent amplification through the *Nature News* interview, which transformed a limited clinical case into a global media phenomenon. Finally, careful attention must also be given to the content of the *Rejuvenation Research* article, which carries the potential to inspire future practices—just as it did in the case of Beata Halassy.

Self-Therapy, Ethical Committees, and Reproducibility

Beata Halassy did not strictly conduct a self-experiment, as her story does not originate from an experimental idea or a research project. Instead, it stems from a very particular clinical history: her own. This represents a point of departure from traditional self-experiments, configuring it more as experimental self-therapy. As such, comparing her case and traditional self-experiments of the past century is not entirely appropriate, though it highlights a crucial point that may become increasingly relevant for patients who are also physicians or researchers and choose to undergo personalized therapies independently. Other contemporary practices described as forms of self-experimentation take place in a different and less visible context: some patients choose to engage in experimental self-therapy when official treatment pathways fail to provide answers[29], or as a deliberate challenge to the rules of conventional clinical research. In such cases, the boundary with fraudulent therapies can easily be crossed; however, this issue lies beyond the scope of the present article.

Indeed, Halassy and co-authors insist on referring to their self-therapy as self-experimentation and decide that, as such, it does not require ethical committee review. This plausibly explains the publication difficulties encountered by Halassy before approaching *Vaccines*. Unlike other scientific journals, *Vaccines* had previously published articles containing self-experiments without ethical approvals, which were then referenced in Halassy's article to justify the lack of ethical committee authorization. However, the issue is far from resolved[30]. The point is that, regardless of whether ethical committees approve self-experiments or self-therapies (there are no statistics in the literature, but ethical committees with relevant regulations exist, such as those at Tufts University[31] and at Houston University[32]), the decision to publish an article rests with the editorial boards[33]. Evidently, *Vaccines* chose to diverge from the practice of other scientific journals and accept articles without ethical authorization.

This highlights a possible problem for an increasingly personalized medicine: the lack of rules and controls, both on experiments and their publication, seems to reopen the door to self-experimentation. This is well explained, albeit with somewhat triumphant tones, in William Bains' 2007 article: "Biomedical research need not be carried out solely by 'Them': distant, dissociated, enormously costly institutions and companies. It can, and increasingly in the 21st century will, be carried out by 'Us', the

informed non-professional. Conventional clinical trials treat humans with the same experimental model as laboratory rats - regarding them as mute, variable, unreliable material from which results must be obtained as fast as possible to maximise return on investment and patent life. The alternative is longer term, self-reported clinical studies of new treatments, based on the assumption that the experimenter is informed, intelligent and aware. A wide variety of new treatments for chronic disease are available, involving elements of diet, behaviour, environment and non-prescription medication as well as ethical pharmaceuticals, and previous experience suggests that they can be enormously effective. The key is objective, quantifiable measures of outcome. These can be achieved with over-the-counter diagnostics for a variety of parameters, as well as with self-built test systems, and careful and systematic observations of symptoms. Hypothesis generation is a key part of this process" [34].

Beata Halassy maintains that her high professional specialization allowed her to understand, to the best of her ability, the state of the art in virological research and the potential risks of self-therapy. However, not all self-experiments are conducted under conditions of complete information. This certainly occurs in biohacking, where individuals not always scientifically prepared undertake experiments[35].

This points to other reasons why publications like those of Hanley and Halassy are problematic: they may provide technical suggestions to those who navigate the secretive realms of unofficial biomedicine[36], and create gray areas between correct practices accepted by most and arbitrary exceptions decided by individual research groups and validated by a single editorial board. This was particularly evident during the initial stages of the COVID-19 pandemic, when the urgency to develop and distribute a vaccine pushed some unofficial groups to practice self-experimentation with do-it-yourself vaccines, reigniting, at least in some contexts, the ethical discussion[37].

Halassy and colleagues write that their research is not replicable by others because Halassy found herself in the unusual position of being both an expert virologist and an oncology patient, thus able to manage the experimentation independently. This admits that the case is extraordinary and only another expert virologist with the same disease could benefit from the technical indications contained in the paper. This, while potentially relieving the scientific journal *Vaccines* from ethical criticism for publishing the paper, and the researcher from criticism for the risk of emulation, renders the publication debatable on another front: that of reproducibility. This is a crucial point in the discussion on self-experimentation, one of the main factors that led to its decline in the 20th century, as research methods based on large-number statistics became established[38].

Historical Citations

In the article by Hanley et al., as in Weisse's article, the practice of self-experimentation is often recalled nostalgically, as part of a noble tradition, albeit no longer au-

thoritative from the standpoint of knowledge production. For instance, American physicians often quote[39] the self-experiment of Walter Reed and colleagues, in the search for the origin of yellow fever. However, in its heroic version, celebrating American medicine, there is often an omission of Reed's own flight in the night, whereby he evaded the self-experiment to which two of his collaborators instead subjected themselves (one of whom died as a result) [40].

The instrumental use of self-experiment in reconstruction of Hanley et al. is highlighted by the distorted narratives provided, in particular about the Nobel-winning discovery of the link between the bacterium *Helicobacter pylori* and gastrointestinal ulcer. This discovery was made possible by the self-experiment performed by the Australian physician Barry Marshall after years of research into the issue and discussions with several colleagues. In 1984, Marshall resorted to self-experiment because he could not infect experimental animals: in order to prove the link between the bacterium and the disease, he drank a glass of the germ culture he prepared. His supervisor Robert Warren was fully aware of the n=1 trial, that resulted in a severe mucosal inflammation (diagnosed by a gastroscopy), a series of symptoms (nausea, halitosis): all of the signs disappeared within two weeks following an antibiotic treatment[41].

While the paper of Hanley et al. underlines the supposed secrecy of the experiment, historical reality is quite different: Marshall openly discussed his theory and his unconventional procedure with other people, including colleagues, lab technicians and his family (albeit, the wife only knew it a few days after the ingestion of the broth). After the *Lancet* publication about the *Helicobacter* theory of gastritis and ulcer[42], rumors about the self-experiment were going around and reached to an American tabloid journalist, who called Warren. The story was thus public, and others papers were published to reinforce the theory[43]. Soon afterwards, other scientists replicated Marshall and Warren's results[44]. Ten years after, Marshall's hypothesis became widely accepted, because of the resistance of the medical community, and in 2005 he shared the Nobel prize for medicine and physiology with his supervisor Robin Warren.

Hanley's et al. paper also misrepresents Werner Forssman's first catheterism in 1929: in this case, the secret was needed because – quite correctly – nobody was willing to allow such a risky operation. Forsmann was officially refused permission for the procedure[45], so that he had to do it secretly (though within the hospital he was working in, and with the help of a nurse). However, soon after the success, his boss treated him with a fine dinner and Forssman went on to publish a paper describing his *Selbstversuch* (self-experiment).

Clearly, Hanley's rhetoric is meant to create a somewhat mythical tradition of secret, good, and heroic self-experimenters struggling against a caste within the official medicine whose aim is to maintain the power over the production and circulation of knowledge. Looking at the historical reality helps in debunking such rhetoric.

Appeal to a Tradition

The core of Hanley's article is the survey of American clinicians and the census published in Weisse's 2012 article[46].

The small numbers in the survey do not allow for assertions, yet the authors use them to claim "no one in the medical field wants to confess to practicing self-experiments," which is objectively unsubstantiated". Moreover, the paper does not include the text of their questionnaire or the responses received, preventing the reader from forming an opinion.

Secondly, the authors downplay the risk of serious harm and incidents, a fundamental issue in the ethics of self-experiments, and point to Weisse's tables to claim that mortality from self-experimentation is slightly above 1%, comparable to orthopedic surgery. However, Weisse's census, correctly considering only well-documented cases, did not account for those where the experimenter died before leaving testimony of their failure. Most importantly, it does not claim completeness. Weisse's goal is made clear in the conclusions: "Perhaps as we progress into a new era of molecular biology, which is characterized by the development of increasingly complex methods of research, the need for self-experimentation will vanish. My own conclusion is that, despite some unwise decisions in the past to indulge in this activity, many self-experiments have proved invaluable to the medical community and to the patients we are seeking to help. Therefore, rather than scorn such intrepid colleagues in their search for truth, I am inclined to salute them"[47].

Hanley and colleagues further add that some risks of self-experiments are clearly unknown to those first experimenting with a new technique or technology, as was the case for the Curies and radiation, but if the researcher has accepted the possibility of these risks existing, their position is analogous to that of someone practicing a risky sport. Therefore, they argue, the decision to allow them to practice it or not is an ethical matter pertaining to individual freedoms. And also, since it concerns medicine and not extreme sports, to potential benefits: a phrase not further substantiated.

Beyond Hanley's argument, careful consideration must be given to the last lines of the paper: Hanley presented data from his self-experiment to the FDA, but the FDA evidently did not respond as he hoped.

Ethics and the reference to the Nuremberg Code

In Hanley's paper the Nuremberg Code is mentioned as the only international medical regulation that explicitly talks about self-experimentation, with principle number 5: "No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects".

The sentence is ambiguous: if an experimenter assumes the risk of harm to themselves, does this justify exposing subjects to the same risk? Moreover, what is the significance of the term "perhaps"?

The origin of principle 5 remains unclear[48]. Contemporary scholarship supports the notion of shared authorship between Ivy, Alexander, and the tribunal judges[49]. However over the decades, two physicians–Andrew Ivy and Leo Alexander–have each claimed principal authorship of the Nuremberg Code. Notably, both Ivy and Alexander denied responsibility for including the term "*perhaps*" in principle 5[50]. It has thus been suggested that the judges revised this article to pre-empt objections from the defence of the Nazi physicians, who were known to draw parallels with ethically questionable experiments conducted in the United States[51].

In the correspondence with Maurice H. Pappworth[52]–who was at the time preparing his seminal work on human experimentation[53]–Ivy affirmed that principle 5 was inspired by some medical Golden Rule[54], according to which a physician ought to be the first to undergo any proposed treatment. However, he also remarked that the inclusion of "perhaps" diluted the principle, potentially implying the superior value of the physician over other patients.

Regardless of the origins of this ambivalence towards self-experimentation, the American bioethicist Annas[55] has noted that principle 5 appears to characterize self-experimentation as a form of self-abuse–an exploitation of one's own body to elicit public acclaim. This instrumentalization of the self is among the principal reasons why self-experimentation is not embraced within contemporary medical ethics. The use of "perhaps" implies that such self-abuse might be permissible under specific circumstances, thereby introducing an element of ethical uncertainty.

As bioethicist J.K. Davis has observed, the involvement of the researcher as a subject does not inherently render an experiment ethical; rather, self-experimentation must be evaluated according to the same standards applied to any research involving human participants[56]. Nevertheless, recent advancements in biomedical science necessitate the development of novel regulatory frameworks[57]. For instance, neurohacking and gene editing often involve highly individualized procedures with a limited patient cohort.

In this framework, the reference to principle 5 of the Nuremberg Code in Hanley et al.'s article, used to support the argument that self-experimentation is ethically acceptable, seems too unsubstantiated.

It should be finally noted that the Nuremberg Code is not the only international bioethical document to refer to self-experimentation. The Declaration of Helsinki, in its more recent versions (Articles 25–32 concerning informed consent and Article 37 concerning unproven medical interventions)[58], also allows that a physician may act simultaneously as researcher and subject, provided that the experimentation is conducted in accordance with shared scientific and ethical principles. The reference to

self-experimentation in the Declaration of Helsinki is indirect, with its core principles being applicable to situations where the researcher and subject are the same person. In any case, even though no international document absolutely prohibits self-experimentation, one should emphasize both the interpretative difficulties of these texts—particularly with regard to the role of ethics committees—and the notable absence of any reference to the responsibilities of scientific journals.

The Role of Scientific Journals

By long-standing convention, scientific journals have assumed a crucial role as gatekeepers in upholding ethical standards and preventing the dissemination of unethical medical research. However, this position is inherently risky, as these journals are largely operated by private publishers who may not always prioritize the supreme interest of science over their own private interests[59]. While journals aim to enforce ethical standards through rigorous editorial policies, peer-review processes, and adherence to international guidelines[60] such as those from the International Committee of Medical Journal Editors (ICMJE)[61] and the Declaration of Helsinki, the potential for conflicting motivations remains a serious concern. Importantly, the validation conferred by publication in a scientific journal does not merely certify compliance with academic standards but also amplifies the visibility of research, transforming what might otherwise remain a matter of anecdote or news report into a scientific event[62]. In this sense, journals function not only as custodians of methodological and ethical rigor, but also as powerful mediators of scientific information to the wider public—an aspect clearly illustrated by the Halassy case, where editorial decisions effectively shaped the narrative and authority of the research.

The role of these journals in the absence of clear, universally shared rules on self-experimentation raises therefore a general critical concerns. The Hanley and Halassy cases clearly demonstrate how the discretionary application of ethical norms can leave editors free to make questionable and counter-current decisions, such as deeming an ethics committee's approval unnecessary for studies and therapies conducted by the very researcher who conceived them. Consequently, this discretionary power allows for the publication of research articles that would likely be rejected in most other contexts, thereby establishing a precedent. These articles can then be cited as bibliographic references for subsequent, similar studies, creating a feedback loop that undermines established ethical standards.

Furthermore, it is plausible that the future expansion of alternative publishing channels—such as preprint archives, blogs, and predatory journals—will make it even easier to publish articles that lack proper controls and verification[63]. In particular, the rise of predatory journals undermines the gatekeeping function by bypassing rigorous peer review and ethical oversight, allowing unethical or low-quality research to enter

the literature[64]. Additionally, research misconduct—including fabrication, falsification, and lack of informed consent—remains a significant issue, with retraction of articles serving as a primary corrective measure. However, even reputable journals are not immune to publishing unethical research, as high retraction rates in leading journals demonstrate[65,66]. In conclusion, it is evident that mere editorial oversight is insufficient to contain this problem and ensure the ethical integrity of research involving self-experimentation.

Conclusion

The practice of self-experimentation was widespread in medical research until the latter half of the twentieth century[67], and it is indeed responsible for several significant scientific and clinical advancements[68]. Although never standardized, it was for many years regarded as an accepted norm. Over time, however, it has been largely abandoned due to a combination of ethical and methodological concerns, which render it largely incompatible with contemporary standards of biomedical research[69].

Methodologically, self-experimentation is inherently limited by the fact that the sample size is, by definition, one. This makes any findings statistically non-generalizable and unreliable. Moreover, as it is not the outcome of random observation, self-experimentation does not even fulfil the criteria for a case report. It lacks a control group, and because the investigator and the subject are the same individual, it becomes virtually impossible to implement blinding procedures–whether single or double-blind–or the use of placebos. These methodological shortcomings severely compromise the ability to eliminate bias, and significantly hinder reproducibility.

From an ethical perspective, the analysis of self-experimentation can be framed in light of Beauchamp and Childress's canonical principles[70]: autonomy, beneficence, non-maleficence, and justice.

In self-experimentation, the principle of autonomy appears to be expressed in its most radical form, since the individual freely elects to assume risks for themselves. Yet this very emphasis on autonomy accentuates the fragility of the other bioethical principles, particularly beneficence and non-maleficence. The dual position of investigator and subject renders impartial evaluation almost impossible: the absence of an independent assessor creates a situation in which methodological rigor and adequate risk–benefit assessment are systematically undermined. This problem is exacerbated when, as in the forementioned cases, recourse to an external ethics committee is intentionally avoided from the outset, thereby stripping the process of the institutional safeguards normally required in research involving human participants. The resulting scenario epitomizes one of the most delicate issues in the ethical debate: the possibility of an individual simultaneously embodying the roles of both researcher and participant. While prohibiting a person from undertaking procedures on their own body may seem, in principle, a way

to address this dilemma, such prohibition collides with deep-seated legal and cultural obstacles and, in practice, is almost impossible to enforce[71]. Moreover, it complicates the mandate of ethics committees, which may be compelled to intervene in order to restrict acts of bodily self-disposition by reference to national legislation. In the Italian context, for example, Article 5 of the Civil Code explicitly forbids "acts of disposition of one's own body that cause a permanent reduction in physical integrity, or that are otherwise contrary to the law, public order, or morality". This provision underscores the inherent tension between personal autonomy and the collective responsibility of institutions charged with protecting both individual subjects and the integrity of biomedical research.
The principle of justice highlights the need to assess whether and how knowledge produced through individual practices can generate collective benefits without reproducing new inequalities. In facts, self-experimentation has the potential to generate new forms of inequality: only a restricted group of individuals—most often affluent and highly educated scientists—are in a position to assume such risks, while society at large ultimately accrues the potential benefits or suffers the possible harms. In this sense, it is not merely a matter of personal autonomy, but a structural issue of distributive justice and social responsibility in biomedical research.
The ethical concerns become even more pronounced when the practice shifts from self-experimentation to self-therapy. Whereas self-experimentation may, at least in principle, aim to generate knowledge of potential collective benefit, self-therapy is primarily directed toward individual gain. This asymmetry intensifies the imbalance between risks and benefits: the individual assumes potentially life-threatening risks without producing outcomes that can be meaningfully generalized to others. From the perspective of Beauchamp and Childress's principle of justice, such practices fail to ensure an equitable distribution of burdens and benefits, effectively privatizing both the risks and the rewards of biomedical knowledge. Moreover, when cases of self-therapy are publicized or validated through scientific channels, they risk encouraging emulation by more vulnerable patients who lack the competence or safeguards to critically evaluate such practices. For these reasons, self-therapy should be regarded as even less ethically defensible than self-experimentation, as it undermines both the integrity of research and the requirements of distributive justice.
Finally, a general ethical view on the case raises the classical issue of the relationship between individual autonomy and institutional paternalism[72]. Is it legitimate to allow a scientist (or a patient) to assume life-threatening risks in the name of research? Or in the name of therapy? Should the scientific community and healthcare institutions establish non-negotiable boundaries, even against the individual's will[73]?
Moreover, the decline in self-experimentation is primarily attributed to concerns over risk assumption. It has been observed[74] that investigators may be more willing to expose themselves to physical risk than would a subject not directly involved in the research. Furthermore, in collaborative research environments, junior scientists may

experience implicit or explicit pressure to engage in self-experimentation, thereby contravening the foundational principle of the Nuremberg Code, which mandates that consent must be voluntary, fully informed, and free from any form of coercion.

It should also be noted that there is no universally accepted or operational definition of "self-experimentation." As a result, as happens for instance in Hanley's article, procedures involving the researcher undergoing minor interventions such as blood draws or minimally invasive diagnostic techniques–often alongside other subjects–are classified as self-experiments. Similarly, the scientific literature includes instances of entirely benign self-experiments addressing simple inquiries, such as those related to mood, sleep patterns or weight management[75], as well as those concerning the use of personalized technologies, such as smartphone applications, designed to empower patients in monitoring the impact of diet on specific gastrointestinal conditions[76]. A noteworthy example is that of Stanford molecular geneticist Michael Snyder[77], who conducted extensive genomic analyses on himself, ultimately diagnosing diabetes well in advance of clinical onset. While this procedure is arguably better characterized as self-monitoring, Snyder referred to it as "truly personalized medicine".

Today, in a context characterized by cheaper technologies, an increased emphasis on personalization, and, above all, the pervasive use of social networks, the practice of self-experimentation is re-emerging in novel and highly visible ways[78,79]. During the COVID-19 pandemic, significant instances of vaccine self-experimentation—conducted outside formal clinical trials—brought renewed attention to the ethical, medical, and regulatory risks at stake, as well as to the urgent need for shared frameworks to govern such practices[80,81,82].

Prior to this, self-experimentation in the field of genetics had led to the commercialization of DIY gene-editing kits that were not validated through official or standardized methods. In response, the U.S. Food and Drug Administration intervened, explicitly warning against the potential dangers of unregulated gene therapy products[83].

These examples reveal a common feature: they consistently involve forms of "unofficial" or "parallel" medicine, which deliberately operate outside the boundaries of institutional research protocols and established regulatory safeguards. The tension between individual autonomy and institutional paternalism becomes particularly salient in the case of biohacking and DIY biology, where individuals and communities consciously position themselves at the margins of established systems of oversight. While such practices are often framed by their proponents as expressions of freedom, autonomy, and even resistance to bureaucratic inertia, they simultaneously raise profound concerns regarding safety, dual-use risks, and the legitimacy of scientific knowledge generated outside accredited research institutions.

One central issue concerns regulatory evasion. Unlike research conducted within academic or clinical institutions, DIY bio projects typically fall outside established oversight frameworks such as institutional review boards, biosafety committees, and

clinical ethics committees[84]. While this absence of regulation may be justified by reference to individual freedom and the ethos of open science, it simultaneously exposes participants and the broader public to unassessed risks. In the medical domain, this means that diagnostic, therapeutic, or enhancement-oriented practices may proceed without guarantees of safety, efficacy, or accountability.

A second challenge arises from dual-use risks[85,86]. The convergence of biotechnology with digital tools—such as open-source software, machine learning, and bioinformatics—reduces the barriers to potentially hazardous experimentation. In contexts where oversight is minimal, the possibility that DIY bio knowledge or tools might be repurposed for harmful ends, intentionally or accidentally, cannot be ignored. This concern has become especially salient in the aftermath of the COVID-19 pandemic, during which DIY groups experimented with unregulated diagnostic tests and protocols in Us as in Europe[87].

A further issue is that of scientific legitimacy. Traditional biomedical research derives its authority from methodological rigor, peer review, and reproducibility. By contrast, DIY bio projects may produce results of uncertain epistemic value, since they often bypass the validation mechanisms of institutional science[88]. This lack of legitimacy is not merely epistemological but also ethical: citizens engaging in self-directed medical experimentation may be misled about the reliability of outcomes, thereby undermining informed consent and responsible decision-making.

In sum, the ethical analysis of DIY biology and citizen science in medicine highlights tensions between freedom and oversight, innovation and dual-use risk, participation and legitimacy[89]. These tensions mirror, in contemporary form, the longstanding dilemmas of self-experimentation: the line between scientific autonomy and ethical responsibility remains deeply contested.

The case of Beata Halassy marks a change, demonstrating that self-experimentation today can take place within the context of academic scientific practice. Indeed, the case concerns a highly specialised cancer therapy that, although conducted outside a conventional experimental protocol, was carried out within a university medical laboratory and followed by a regular peer-reviewed scientific publication.

This development raises important issues that deserve careful consideration.

When looking at self-experiment in historical perspective, the concept of "knowledge economy" introduced by Jurgen Renn[90] may be useful. Today, and in the last five decades, the production and circulation of biomedical knowledge take place in a highly complex system where the stakes are incredibly high: ethical standards, financial involvement, instant and global communication networks have introduced biomedical research in a new dimension, requiring practices that privilege safety over innovation.

At the same time, the landscape of healthcare is undergoing a significant transformation, marked by an increasing emphasis on individualized approaches to health[91]. This shift recognizes the inherent variability among individuals and the limitations

of a uniform, "one-size-fits-all" model in addressing complex health challenges and moves towards the model of medicine that Leroy Hood has called the 4Ps (predictive, preventive, personalised, participatory)[92].

Thus, Halassy's case highlights the delicate balance between the doctor-patient's pursuit of the best treatment for himself within the framework of personalised medicine (and, by extension, autonomy over his own body), and the limited scientific significance that self-treatment may have for the wider scientific community. Therefore, the case also raises concerns about its public communication.

As a cancer patient, Halassy suspended her standard therapies for a period of three months, subsequently claiming that her self-administered treatment had proven effective. The risk of emulation thus includes the potential for patients to reject standardized therapies and forgo treatment protocols with proven and measurable efficacy. In today's medical context, such behaviour is deemed unacceptable, particularly if endorsed by academically authoritative figures[93]. In this, the role of scientific publications as a possible gatekeeper of scientific information to the general public must be considered, within the perspective of the crisis of the peer review system[94]. Thomas Ploug, for instance, argued[95] – specifically in relation to two studies on the use of statins that questioned their safety and were extensively covered by the general press, leading to a well-documented decline in treatment adherence among patients[96]– that the publication of certain studies should be subject to stricter control or even prevented. A particular case is that of biological warfare and the potential use of medical research for military purposes[97]. Given the potential harm such publications can inflict on the public, Ploug proposed that internationally recognized ethical publishing codes should include a clause assigning the editor-in-chief of a medical journal moral responsibility for the health-related consequences of the research they choose to publish. This issue had already been strongly emphasized by Atlas et al. in the aftermath of the September 11, 2001 attacks, through a statement published in the journal *Science*[98].

In conclusion, this case highlights the necessity and urgency of a thorough reflection by healthcare professionals on self-therapy and self-experiments, within the framework of personalized medicine. In general, self-experimentation continues to represent an ambivalent domain, suspended between individual freedom and collective responsibility. It challenges the boundary between research and therapy, between autonomy and protection, between innovation and risk. This is a pressing question that resurfaces today in debates on biohacking, experimental therapies for rare diseases, and the role of scientific institutions.

This case also raises critical questions regarding the scientific publication of such cases and their public dissemination. While publication is essential to foster academic debate, it also introduces new risks associated with the widespread accessibility of scientific information and technologies. The ultimate goal must be to ensure that

medical progress is achieved in accordance with fundamental ethical principles and through scientifically valid and reproducible methodologies, while simultaneously safeguarding public health.

The ultimate question remains open: to what extent can society accept that the production of biomedical knowledge proceeds through unregulated bodies, and who should bear responsibility for the consequences?

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