Pediatric Off-Label Use of Covid-19 Vaccines: Ethical and Legal Considerations

by ELIZABETH LANPHIER and SHANNON FYFE

Can Covid-19 vaccines be used off-label? Should they be? These were questions on the minds of parents, pediatricians, and the media when the U.S. Food and Drug Administration fully approved the Pfizer-BioNTech Covid-19 vaccine (Pfizer vaccine) for people aged sixteen and up. That same day, the American Academy of Pediatrics (AAP) cautioned against pediat-

ic off-label use of the vaccine,1 citing dosing differences between pediatric and adult vaccine recipients. They en-
couraged expedited review and authorization of pediatric Covid-19 vaccines rather than off-label use.

There are three Covid-19 vaccines now available for use in the United States: the fully approved Pfizer vaccine and two vaccines that are available only under an emerg-

cy-use authorization (EUA) in adults: the Moderna Covid-19 vaccine and the Johnson & Johnson/Janssen Covid-19 vaccine. The Pfizer vaccine was also initially authorized for individuals sixteen and older.2

We are focused on questions pertaining to pedi-

tric off-label use of the Pfizer vaccine in children under twelve in light of the approved BLA for the Pfizer vaccine for individuals sixteen and older.3

Popular and social media reflected additional con-

cerns, including legal and ethical permissibility, legal and clinical precedent, and perceived or presumed risks to patients, providers, and society of off-label vaccination. Certain questions about legality and malpractice revealed that both medical professionals and the public misunder-

stood established legal precedent that allows providers to engage in clinically and ethically appropriate off-label use. If legal liability is avoided by ensuring that clinical decisions are ethically appropriate, then the question be-

comes how to assess ethical permissibility. Theoretically, the same legal and ethical norms apply to pediatric off-la-

bel Covid-19 vaccination as to other instances of off-label use. Based on our analysis, there is no singular answer to the ethical permissibility of off-label pediatric Covid-19 vaccine use; the ethics depend on the benefits, risks, and alternatives for each patient.

Yet in practice, the U.S. Covid-19 vaccination pro-

gram departs from policy and practice norms for off-

label vaccination. The Centers for Disease Control and Preventons’s (CDCs) vaccine provider agreement (VPA) sets the terms and conditions for the use of federally pur-

chased Covid-19 vaccines and therefore of all Covid-19 vaccines administered in the United States outside of clinical trials, since all Covid-19 vaccines for U.S. resi-
dents have been purchased and supplied by the U.S. government. According to the VPA, administering vac-
cines to individuals younger than the ages for whom the FDA has approved or authorized use is prohibited and risks repercussions to providers, including legal liability, loss of payment, and removal from the Covid-19 vaccine program. The VPA effectively prevents providers from even considering recommending or administering pediat-
ric Covid-19 vaccine off-label.

The prohibition reveals a tension between health policy and individual health care choices and options, as well as the distinct ethical consider-

dations that combine.

After briefly contextualizing ethical and legal pre-

cedents regarding off-label use, we offer an analysis of the ethical permissibility of and considerations for pediat-
ic off-label Covid-19 vaccination based on individual benefits, risks, and available alternatives. Our analysis challenges the ethics of the blanket prohibition against off-label pediatric Covid-19 vaccination in the VPA; as it blocks clinicians from providing the care they may de-
termine to be clinically and ethically appropriate for their patient. At the same time, our analysis acknowledges that

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Covid-19 creates population-level ethical considerations that are at times in tension with individual health interests.

**Off-Label Use**

Once a pharmaceutical meets the safety and efficacy standards required to receive FDA approval (that is, an approved BLA), it can be used for new indications or in populations for which it was approved. Either use, whether for a new indication or in a different population, is considered off-label. Such off-label use can minimize the costs of additional clinical trials and increase efficiency of prescribing options. Medical providers do not face additional liability by prescribing or recommending FDA-approved medications or vaccines off-label, as long as they are following appropriate clinical and ethical practice. Courts have consistently sided with providers in such cases.7 Studies suggest that 10 percent to 20 percent of prescriptions written for off-label use are appropriate, although this figure is higher in certain populations, such as children. Federal regulations on research in populations identified as vulnerable, which according to the U.S. Code of Federal Regulations include children, “pregnant women, human fetuses, and neonates”; and “prisoners,” create obstacles to conducting clinical trials in these populations. Additionally, members of these vulnerable populations, as well as others not explicitly named by the regulations, may be less inclined to participate in clinical trials (although, as we discuss below, this has not proven to be true for parental willingness to enroll in pediatric Covid-19 vaccine trials). For these reasons, people in these groups are disproportionately reliant upon off-label use for access. For example, one systematic literature review found that more than half of pregnant women use at least one prescription medicine during pregnancy.8 Since few drugs are approved for use during pregnancy, taking medicines during pregnancy largely means using them off-label, although that does not change the FDA’s authority for individuals to self-report their experiences taking medications while pregnant. The permissibility of off-label use may be a further disincentive for enrolling participants in pediatric trials. Studies in pediatric settings suggest that off label and possibly as many as 70 percent of in-patient stays 10 in children for whom no vaccine has yet received an EUA, he primary benefit of off-label Covid-19 vaccination in children for whom no vaccine has yet received an EUA, the AAP recommendation against pediatric off-label use is intended as a public health tool, but it is a medical strategy to confer protection to individuals who are not covered by off-label use during outbreaks. For example, the measles-mumps-rubella (MMR) vaccine is a core component of outbreak preparedness. For outbreaks brought by travelers, the state of trials needs to be weighed against the known and unknown short- and long-term risks of vaccination, could be a benefit for some patients. These uncertainties may present with an unanticipated side effect. Individuals should present with an unanticipated side effect. Individuals should have had a prior history of the same condition. One might argue that it is ethically necessary to await clear and convincing evidence that Covid-19 vaccines are safe and efficacious in children. That pediatric clinical trials are ongoing raises concerns about safety risks because the very data being collected are the data that would inform an assessment of vaccine safety. Pediatricians or parents may worry that children could experience dangerous side effects not seen in adults. Yet the state of trials needs to be weighed against already known information about safety and efficacy that exceptionally rare side effects could emerge that trials will not uncover—for example, already known by the FDA.

Some assume that off-label-use guidelines are not intended as a public health tool, but it is a medical strategy to confer protection to individuals who are not covered by off-label use during outbreaks. For example, the measles-mumps-rubella (MMR) vaccine is a core component of outbreak preparedness. For outbreaks brought by travelers, the state of trials needs to be weighed against the known and unknown short- and long-term risks of vaccination, could be a benefit for some patients. These uncertainties may present with an unanticipated side effect. Individuals should have had a prior history of the same condition. One might argue that it is ethically necessary to await clear and convincing evidence that Covid-19 vaccines are safe and efficacious in children. That pediatric clinical trials are ongoing raises concerns about safety risks because the very data being collected are the data that would inform an assessment of vaccine safety. Pediatricians or parents may worry that children could experience dangerous side effects not seen in adults. Yet the state of trials needs to be weighed against already known information about safety and efficacy that exceptionally rare side effects could emerge that trials will not uncover—for example, already known by the FDA.

**Off-label vaccination during an outbreak is not intended as a public health tool, but it is a medical strategy to confer protection to individuals who are not covered by off-label use during outbreaks.**
Therapeutic decision-making must always rely on the best purpose of off-label use is to benefit the individual patient. The off-label use, which was reaffirmed in November 2020, states, “The ethics of off-label use count for more than the off-label use of an approved therapy for a given indication should not be administered off-label at all. Until Moderna and Johnson & Johnson apply for and receive an approved BLA for any indication or population, is considered off-label. Such off-label use can low the same ethical and legal norms as off-label prescrib- ing, grounded in legal permissibility and ethical analysis of clinical risks, benefits, and alternatives. The anticipated risks and benefits to a potential off-label vaccine recipient may be different from the risks and benefits of receiving an off-label prescription for disease treatment. The novelty of the SARS-CoV-2 virus and Covid-19 vaccines further complicates this assessment, given the ongoing collection of new scientific information about risks and benefits.

Some evidence suggests that third doses of Pfizer vac- cines, or “booster” shots more generally, have been sought and administered “off-label” in adults. Initially, the FDA au- thorized third doses of only the Pfizer vaccine, and the FDA and CDC guidance indicated that this was for use in im- munocompromised individuals, people aged sixty-five and over, and adults (people eighteen and over) at high risk of se- vere Covid-19 or experiencing increased workplace exposure to Covid-19.11 Yet individuals falling outside these groups, and many obtained, third doses of vaccines.12 The FDA has now authorized third doses of the Moderna vac- cine for the same categories as for the Pfizer third doses, and second doses of the Johnson & Johnson vaccine in any adults, as well as mix-and-match additional doses (meaning that people can receive an additional dose from a different manufacturer than that of their original vaccine). However, prior to these authorizations, some individuals sought a dose of an mRNA vaccine on top of a single dose of the Johnson & Johnson vaccine, having determined their own risks and benefits; despite there being no mRNA vaccine au- thorized by the FDA for this purpose at the time.13 Without an FDA-approved BLA for any indication or population, the Moderna and Johnson & Johnson vaccines cannot and should not be administered off-label at all. Until Moderna or Johnson & Johnson apply for and receive an approved BLA, only the Pfizer vaccine could be ethically and legally administered as an off-label “booster” dose to individuals who fall outside the authorized age or indications for an additional dose.

Benefits

The primary benefit of off-label Covid-19 vaccination in children for whom no vaccine has yet received an EUA, let alone full approval, is the possibility of faster and more effective protection against the SARS-CoV-2 virus. Early in the pandemic, Covid-19 cases were relatively low among children, and those children who became infected tended to have fewer symptoms and less severe cases. However, the advent of the Delta variant has resulted in higher rates of infection in young people, as well as more severe symptoms, increased hospitalizations, and deaths.14 As of February 2021, an estimated 140,000 children in the United States have developed Covid-19, and severe disease from Covid-19 increase, so do the benefits of having some immune pro- tection through vaccination. The risks of remaining unvac- cinated and the potential benefits of vaccination are most heightened for children with underlying health conditions that increase their likelihood of developing severe disease.15 There remains uncertainty about which health conditions these are following FDA authorization of Covid-19 vaccines for children. Yet the risk of long Covid in children who develop mild cases also re- mains uncertain,16 and the ability to weigh this potential risk alongside known short-term risks of Covid-19 infection, and against the known and unknown short- and long-term risks of vaccination, could be a benefit for some patients. These uncertainties indicate a potential role for advisory boards to generate relevant guidance.

In addition to the direct health benefits, vaccination may be a tool to increase some children’s consistent participation in in-person learning. Vaccination could add an additional layer of protection for children, which could be especially helpful for those who are medically vulnerable or in class- rooms where evidence-based mitigation strategies are not adopted. In these situations, having children remain un- vaccinated could risk impeding their social, emotional, and educational opportunities.

Risks

A noted, the AAP recommendation against pediatric off- label use of the vaccine was based on uncertainty about doses and approval required for small children. As the first trials were completed with satisfactory results, the more reliable the data are as guide- posts for off-label use. (This risk analysis may also change as a vaccine receives authorization for a new age group. Risks for off-label use in children under five may be mitigated fol- lowing FDA authorization of a vaccine for children ages five to eleven, for example, despite additional dosing differences between these two age groups.) Assessing the risks of off-label pediatric vaccination in- cludes identifying who is administering the vaccine and with what resources. Pediatricians are experienced at off-label use, given the frequency of the practice with their patient popu- lation. This familiarity can mitigate risks that might occur if pharmacists administer doses, because pharmacies gener- ally care for adult patients administer doses to children. Off- label Covid-19 vaccination for children under twelve may therefore be ethically justifiable only when done by a pedi- trician who is an expert in children’s health and physiology, has experience with off-label pediatric use, is comfortable ordering doses corresponding to the physiology of their pa- pediatric patients, and has the available resources to draw and prepare appropriate doses for this patient population. (Pfizer vaccines come in multidose vials and need to be prepared for administration, so the logistics of drawing doses of different amounts should not be a barrier to off-label use but could require specific planning and training.)

One might argue that it is ethically necessary to await clear and convincing evidence that Covid-19 vaccines are safe and efficacious in children. That pediatric clinical trials are ongoing raises concerns about safety risks because the very data being collected are the data that would inform an assessment of vaccine safety. Pediatricians or parents may worry that children could experience dangerous side effects not seen in adults. Yet the state of trials needs to be weighed against already-known information about safety and efficacy that exceptionally rare side effects could emerge that trials will not uncover—a concern already flagged by the FDA. Some assume that off-label-use guidelines are for the treatment of sick people, not preventative pediatric patients. One might, for instance, prescribing a critically ill patient an off-label therapy in a last-ditch effort at saving the patient’s life. But there is precedence for other kinds of off- label use, including vaccines for healthy people during out- breaks. For example, the measles-mumps-rubella (MMR) vaccine was given to military troops who did not meet the clearance required for active duty.11 As the risks of infection and severe disease from Covid-19 increase, so do the benefits of having some immune pro- tection through vaccination. The risks of remaining unvac- cinated and the potential benefits of vaccination are most heightened for children with underlying health conditions that increase their likelihood of developing severe disease.15 There remains uncertainty about which health conditions these are following FDA authorization of Covid-19 vaccines for children. Yet the risk of long Covid in children who develop mild cases also re- mains uncertain,16 and the ability to weigh this potential risk alongside known short-term risks of Covid-19 infection, and against the known and unknown short- and long-term risks of vaccination, could be a benefit for some patients. These uncertainties indicate a potential role for advisory boards to generate relevant guidance.

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Studies in pediatric settings suggest that off-label and possibly as many as 70 percent of in-patient stays 10 in chil- dren’s hospitals in the United States.11 Moreover, the FDA maintains registries for individuals to self-report their medications, or “booster” shots more generally, have been sought and administered “off-label” in adults. Initially, the FDA au- thorized third doses of only the Pfizer vaccine, and the FDA and CDC guidance indicated that this was for use in immu- nocompromised individuals, people aged sixty-five and over, and adults (people eighteen and over) at high risk of se- vere Covid-19 or experiencing increased workplace exposure to Covid-19.11 Yet individuals falling outside these groups, and many obtained, third doses of vaccines.12 The FDA has now authorized third doses of the Moderna vac- cines for the same categories as for the Pfizer third doses, and second doses of the Johnson & Johnson vaccine in any adults, as well as mix-and-match additional doses (meaning that people can receive an additional dose from a different manufacturer than that of their original vaccine). However, prior to these authorizations, some individuals sought a dose of an mRNA vaccine on top of a single dose of the Johnson & Johnson vaccine, having determined their own risks and benefits; despite there being no mRNA vaccine au- thorized by the FDA for this purpose at the time.13 Without an FDA-approved BLA for any indication or population, the Moderna and Johnson & Johnson vaccines cannot and should not be administered off-label at all. Until Moderna or Johnson & Johnson apply for and receive an approved BLA, only the Pfizer vaccine could be ethically and legally administered as an off-label “booster” dose to individuals who fall outside the authorized age or indications for an additional dose.

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theoretical ethical and legal permissibility and how the CDC’s guidance off-label Covid-19 vaccination, establishing its theoretical ethical and legal permissibility and how the CDC’s VPA departs from these norms.

The risks of off-label administration of Covid-19 vaccines to children are modified by the terms of the VPA issued by the patient or surrogate, which includes sharing the risks, benefits, and alternatives of a proposed treatment. Notifying patients that a proposed pharmaceutical is off-label has not historically been a legal requirement for off-label use, but in the case of vaccination, which provides recommendations and administer rather than prescribe, an explanation of why a provider is recommending vaccination off-label would be clinically and ethically relevant.

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The CDC should provide sufficient and transparent reasons for why a provider is recommending vaccination off-label, as well as a reviewer for The Hastings Center Report, for valuable feedback on various stages of this project.

The American Academy of Pediatrics, "The American Academy of Pediatrics Cautions against Off-Label Use of COVID-19 Vaccines in Children under 12," news release, August 23, 2021, https://www.aap.org/en-us/news-room/news-releases/sap/2021/american-academy-of-pediatrics-cautions-against-off-label-use-of-covid-19-vaccines-in-children-under-12.

At the time of writing, Pfizer and BioNTech had submitted their clinical trial data to the FDA and requested approval for emergency use authorization of their vaccine at a 10-microgram dose in children ages two to eleven. Shortly before publication of this essay, the FDA authorized emergency use for this age group. 3. S. Syed et al., “The Law and Practice of Off-Label Prescribing and Physician Promotion,” Journal of the American Academy of Pharmacists and the Law 49, no. 1 (2011): 1-7.

4. M. B. Gillick, “Controlling Off-Label Medication Use,” Annual Review of Medicine 150, no. 5 (2009): 594-647.

5. 45 C.F.R. § 46 (2018).

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7. J. Beall et al., “OFF-Label Drug Use in Hospitalized Children,” Archives of Pediatrics & Adolescent Medicine 161, no. 3 (2007): 256-61.

8. J. T. Dye et al., “Efficacy and Safety of狂热的negligence的per-dose costs of Covid-19 vaccines might keep this barrier low.” The result of the Covid-19 VPA, then, is to place sig-
ificant barriers in the way of providing vaccines off-label.

The CDC should provide sufficient and transparent reasons for overruling standard ethical norms and legal precedent in its provider agreement. Currently, we do not know what their reasons are, though we worry that they are due to the kinds of unspecified or even incorrect inferences many hold about off-label use: erroneous beliefs that it is illegal, that it hampers provider liability, or that it is experimentally

The CDC’s mission to support public health and concerns related to vaccine messaging, confidence, and any-thing that might undermine public health goals or health care/human rights needs could be compatible. Misinformation about legal and ethical considerations relevant to off-label use, which we have tried to clarify here, adds an additional layer of com-

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Omitting them off-label could limit access for those for whom off-label use of Covid-19 vaccines in their VPA. One worry theoretical ethical and legal permissibility and how the CDC’s legal norms that ought to guide medical decision-making relate to children are modified by the terms of the VPA issued by the FDA. In the case of vaccination, which providers recommend and administer rather than prescribe, an explanation of why a provider is recommending vaccination off-label would be clinically and ethically relevant.

The risks of off-label administration of Covid-19 vaccines to children are modified by the terms of the VPA issued by the CDC. Our goal, however, is to consider the ethical and legal norms that ought to guide medical decision-making regarding off-label Covid-19 vaccination, establishing the theoretical ethical and legal permissibility and how the CDC’s VPA departs from these norms.

Finally, there are concerns about the impact of administering Covid-19 vaccines off-label for public health, and these may contribute to the CDC’s prohibition of age-based off-label use of Covid-19 vaccines in their VPA. One worry could be that vaccines remain a scarce resource and that allocating them off-label could limit access for those for whom vaccines off-label are needed. As at scale, this risk could be considerable, and some have argued that children in developed countries should not receive vaccines prior to children in developing countries. Yet the benefits of individual off-label use would be relative to the individual risks, suggesting that instances of Covid-19 pediatric off-label use would be most ethically defensible for high-risk children who are part of vulnerable risk groups themselves.

**Population-Level Challenges**

That individual decisions about Covid-19 vaccination are made in the context of a global pandemic and public health crisis cannot be overstated. While we have focused on individual patient and provider decision-making, we recognize that the decisions are made within obligations to policies and procedures—public health. These obligations are not uniformly approved. At a scale, this risk could be considerable, and some have argued that children in developed countries should not receive vaccines prior to children in developing countries. Yet the benefits of individual off-label use would be relative to the individual risks, suggesting that instances of Covid-19 pediatric off-label use would be most ethically defensible for high-risk children who are part of vulnerable risk groups themselves.

**Alternatives**

One potential alternative to age-based off-label use of Covid-19 vaccines would be to further expand enrollment of children under twelve in clinical trials. The benefits of increased trial enrollment could include access to more study data (by expanding the sample size) and close oversight of dosing, timing, and side effects related to vaccination. Access to vaccines via clinical trials would also guarantee consistent dosing, as well as systems of tracking, monitoring, and reporting adverse events.

There are feasibility constraints for expanding trial enrollment, which requires additional funding and personnel to manage a potential surge of enrollments. Media reports suggest the demand for enrollment of children for Covid-19 vaccine trials greatly outpaces the number of trial slots available, even after the FDA asked the Pfizer and Moderna pediatric Covid-19 trials to increase capacity. Additionally, participating in a vaccine trial does not ensure vaccination. The Pfizer Covid-19 trials in children under twelve administer placebo in one-third of their trials cohort. Enrolling in the trial creates an opportunity for early vaccination, however; study details indicate participants are enrolled within six months and that those who received placebo are offered vaccine doses.

Moreover, expanded trial enrollment would not address the needs of populations who may be the best candidates for off-label use. For example, a child who is receiving a vaccine already authorized or approved (which should be ethically and legally permissible) and meets other conditions that put them at risk of severe Covid-19 complications. Trials recruit only healthy children with no known underlying severe health conditions. For these individuals, the remaining alternative may be for vaccine manufacturers to grant access directly, such as through an expanded access program (also colloquially known as a “compassionate-use agreement”), though there is no evidence that this has been done to date during the Covid-19 pandemic.

**Misinformation and Challenges**

The safety of vaccines off-label could impact perceptions about vaccine safety or add fuel to anti-vaccine fires. Concerns related to vaccine messaging, confidence, and any-thing that may undermine perceptions of vaccine safety or fuel vaccine hesitancy may be contributing factors, but these are public health concerns that generally fall outside the scope of off-label use. More specifically, explaining why Covid-19 vaccination is different from other cases in which off-label use is permitted, the CDC is not trained in enforcing a VPA that removes this op- tion for individual patients.

One way that the VPA does mirror existing practices relates to the government’s role in establishing criteria for off-label use. Once established, the VPA states that it is not regulated by the Food and Drug Administration, and physicians are legally allowed to use drugs approved by the FDA off-label as long as they are not permitted to do so by the terms of the VPA. The cost diverts vaccine doses from vulnerable populations for others for whom vaccines are already authorized or approved. Similar concerns have been raised about “booster” shots for adults. In both cases, limiting vaccination to those whom it would likely significantly benefit is compatible with equity concerns.

Another potential public health challenge for off-label use relates to vaccine messaging and the potential to undermine vaccine confidence or add fuel to anti-vaccine fires. Off-label use is not experimental, but it could be mistakenly interpreted as such. There is also a distinction between offering off-label vaccines as a health tool for high-risk patients (who may be receiving a vaccine already legally available) and making them available as a population health tool (which is neither ethically nor legally permissible). It is also unclear whether using vaccines off-label would make any difference in curbing or reducing vaccine hesitancy. These concerns should not be a reason to make any individual patient decision, but they may contribute to public health concerns surrounding off-label use.

The legal structure created by the CDC’s VPA is the biggest challenge for pediatric off-label Covid-19 vaccination. The CDC has even issued guidance that providers who administer vaccines off-label risk being kicked entirely out of the vaccine program and may not receive payment for those vaccines. The CDC has also warned providers that administering the Covid-19 vaccine off-label may curtail their liability protection under the Public Readiness and Emergency Preparedness Act. Finally, the CDC has warned that patients receiving off-label vaccines may not be eligible “for federal compensatory relief.”

The VPA applies to “[f]ederally purchased Covid-19 vac-
cines,”suggesting that if vaccines could be obtained apart from the federal program, then restrictions on off-rel-
ed off-label use would not apply. Theoretically, providers willing to consider off-label administration for some pediat-
ric patients would be more likely to approve payment for a vaccine already authorized or approved rather than the Covid-19 vaccine off-label directly from pharmaceutical companies. The cost of these doses would likely be borne by patients, creating an additional concern. The Covid-19 vaccine off-label would not be ethically justifiable, as the benefits of individual off-label use would be relative to the individual risks, suggesting that instances of Covid-19 pediatric off-label use would be most ethically defensible for high-risk children who are part of vulnerable risk groups themselves.

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In Service to Others: A NEW EVOLUTIONARY PERSPECTIVE ON HUMAN ENHANCEMENT

by HUGH DESMOND

Evolutionary theory has largely been perceived as supporting liberal views on human enhancement, views in which decisions to enhance are regulated predominantly by the principle of individual autonomy. But cultural evolutionary theory suggests that individual interests are entangled with community interests. Given that enhancement is often tied to increasing social status, a view of enhancement based on service and trust offers better guidance for the challenges of social living than does autonomy.

Although science may be neither necessary nor sufficient for ethical argumentation, evolutionary theory has played a prominent role in the debate about human enhancement. For example, claims that enhancement should be constrained by a fixed human nature or by givenness seem difficult to hold considering how the human species evolved and continues to evolve.1

It is striking how, on account of such arguments, evolutionary theory has broadly been perceived as supporting liberal views on enhancement, in which decisions about whether to enhance are predominately guided by the principle of individual autonomy. And while liberal views can range from the social liberal to the libertarian, in enhancement ethics, the center of gravity in recent literature has tended toward the latter. According to libertarian views, enhancements are to be judged as Millian "experiments in living": as long as they do not actively harm others, they are ethically commendable expressions of individual autonomy.2

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