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Comment on Change to the Definition of “Human Organ” Under Section 301 of the National Organ Transplant Act of 1984. Health Resources and Services Administration, HHS. RIN 0906-AB02.

We are academic economists who study how incentives and other mechanisms affect individual behavior and whose research is concerned with improving public welfare. We are writing in opposition to the proposed rule changes by the Department of Health and Human Services (HHS) that would ban compensation for bone marrow donations. The reasons we oppose the proposed rule change are that it ignores the most critical benefits of offering economic incentives (point 1 below) and prevents the ability to properly assess and improve the benefits of offering incentives (points 2 and 3 below) despite the HHS proposed regulation explicitly stating (Section III. Impact Analysis) “Economic and Regulatory Impact Executive Order 12866 directs agencies to assess *all costs and benefits* of available regulatory alternatives” (*Italics added*). The HHS document also states that “The provisions of this rule will not affect the following elements of family well-being: Family safety, ... parental rights in the education, nurture, and supervision of their children,” and this regulation could prevent parents such as the lead plaintiff in *Flynn v. Holder* from obtaining bone marrow transplants for their children.¹

- 1. The proposed regulation entirely ignores potential benefits to bone marrow recipients.** The motivation for the ban focuses entirely on concerns for potential donors and gives no weight to the consideration of the patients in need of a bone marrow transplant. There are many patients whose health conditions worsen each year waiting unsuccessfully for a matched bone marrow donation. Depending on the patient's race, there is between an 8 and 50 percent chance that there will be no match in the existing registry. As a result, hundreds of patients die each year due to an inadequate supply of donors.² Economic incentives have the potential to motivate more bone marrow donations thereby saving and prolonging the lives of potentially thousands of patients. Indeed, the benefit-cost of adding one potential donor to the registry indicates enormous positive value, between 5 and 7 times the benefit to the cost.³ By entirely ignoring these potential benefits, the proposed regulation fails to accurately present the welfare consequences of the ban.
- 2. The proposed ban will prevent the most policy relevant academic research that is critically needed to determine whether and how economic incentives can be used to save lives.** Alternative research methods that do not directly examine actual incentives for actual bone marrow donations (e.g., surveys), or uncontrolled studies that do not appropriately account for confounding factors (i.e., differences in incentivized and non-incentivized populations), will produce unreliable policy evidence. Recent work, consisting mainly of Randomized Controlled Studies (RCTs) examining economic incentives to motivate blood donations, shows positive results when evaluating actual incentives for actual blood donations in natural contexts. This robust evidence contrasts with earlier results using alternative methods not examining *actual* incentives and donations.⁴ This is not just an academic point; empirical evidence obtained with rigorous methods should be used to inform policy. This rigor should

¹ The lead plaintiff, Doreen Flynn, has three daughters afflicted with Fanconi anemia who may need multiple bone marrow transplants during their teen years.

² Bergstrom, Garratt, and Sheehan-Connor 2009, Tables 2 and 4.

³ *Ibid*, Table 7.

⁴ Lacetera, Macis and Slonim 2013.

apply in general, but it is especially critical in the context of bone marrow donations where thousands of lives are at stake every year and where adopting a ban without appropriate evidence could have disastrous consequences.

- 3. The ban will eliminate the opportunity to offer any form of economic incentive, not just cash payments.** The policy would thus prevent even non-cash rewards that have been shown to significantly increase blood donations with no harm to the quality of the blood supply.⁵ The proposed change will thus prevent many potential types and sizes of incentives that could be effective. Appropriately designed research could shed light on whether different types of incentives and incentive amounts would have different effects on donations, but the proposed regulation would make this type of research illegal.

In addition to inappropriately assessing the cost-benefit analyses, we oppose the ban for the following two reasons. First, allowing for the compensation of bone marrow donors does not mean that donors have to accept the compensation. When offered, donors could still choose to not accept the incentive or could even donate it to charity. Second, donating bone marrow through the apheresis process and donating whole blood or plasma share a critical characteristic: donors provide renewable material that is extracted with minimal risk and that their body regenerates quickly. The US government has never prevented compensation for these other blood products despite deliberations,⁶ thus from this renewable material perspective there is no reason to have different policies for these types of donations.

In summary, the proposed regulation ignores the potential beneficial effects that offering compensation to bone marrow donations will have on the well-being of patients who need a transplant but are unable to find a match in an uncompensated-only donation system. This implies that “*all costs and benefits* of available regulatory alternatives” have not been assessed. Moreover, it makes it illegal to conduct the very research that would be critically necessary to establish the effects that incentives can have on donations. For these reasons, we oppose this regulation proposed by HHS that would ban all forms of compensating bone marrow donors.

Signed,

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⁵ Ibid.

⁶ Starr, 1998.