



## **Defining the Role Government Should Play in Regulating New Sex Selective Technologies**

Every new genetic technology that emerges should trigger questions about its uses, abuses, benefits and dangers. Considering only how procedures affect the individuals who elect them is insufficient; we must also ask how society as a whole will be altered if their adoption becomes widespread. Generations Ahead asked the Food and Drug Administration (FDA) to solicit precisely the kind of information that would allow us to consider these issues from MicroSort -- a sperm-sorting company hoping to move from clinical trial to market approval.

Banning new reproductive technologies, already impossible, is not a desirable course. Even nuanced restrictions such as limiting who and in what situations techniques like sperm-sorting are permissible would require an instrument far more refined than we have. On the other hand, for-profit makers of these technologies can hardly be trusted to self-restrict. Too often, any paying customer is a good one never mind what increasing sales could mean for specific ethnic groups, the status of women, demographic shifts and disability rights.

Sperm sorting, of the variety MicroSort has patented, allows would-be parents to separate X-chromosome sperm from that of Y. If effective, this would enable these individuals to inseminate with sperm only able to produce a child of the sex they desire. Facts about how well the sort works -- the odds that you will actually get the girl or boy you have paid for -- not to mention the difficulty of getting pregnant with insemination in the first place are essential information for consumers.

Equally important, and to date unknown, is who undergoes this procedure, under what conditions and toward what ends. The change of status MicroSort is seeking from the FDA would allow them to market sperm-sorting more broadly. It would ease current restrictions that confine use to avoiding sex-linked diseases and to attempting to produce a child of the opposite sex of his or her siblings.

Generations Ahead sought to understand the FDA's process for granting market approval, all the while respecting the role the agency plays as watchdog for public safety. In the process of deciding whether MicroSort's technique should be more widely available, Generations Ahead asked the FDA to conduct a public hearing. This little-used approach allows stakeholders to have input about the company and, in this case, genetic technology, under review.

We wanted MicroSort to make public data about which ethnic groups have been using or seeking sperm-sorting as well as whether males, females or a rough mix are generally



preferred. This data is critical not only to the FDA review process but for myriad policy conversations about sex selective procedures coming down the road as technologies advance. To demonstrate we were not a lone voice and to increase traction with the FDA, we reached out to a number of reproductive rights and justice allies to sign-on to a letter requesting a public hearing.

In this, Generations Ahead played the familiar role of bridge builder. We spoke up for more information and consideration of social implications, while also opposing government intervention without cause. Some would-be allies felt they could not join us. Their previous battles with the FDA over reproductive technologies such as the morning-after pill left them understandably leery of government involvement in pregnancy, parenting and personal choice.

To date, we have not heard from the FDA directly. However, sources close to MicroSort relayed back to us a very promising outcome of our unprecedented efforts to find a middle ground between private industry, government regulation and social good. The company itself took our public hearing request very seriously -- indicating awareness of the potential ethical dilemmas and public concern their procedure entails.

Moreover, we helped educate our partners advocating for the rights of women about sex selective procedures. This is a first step past a conditioned response that anything that facilitates reproductive freedom must be allowed and anything that calls for government involvement must be stopped.

