

News-Press.

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On April 9, the FDA threatened Bayer with criminal and civil penalties should it not comply with the order requiring new labeling for its Essure birth control device. This ruling comes from the diligence of thousands of women who complained that the device began triggering persistent pain and bleeding. Women have not remained silent.

The FDA has also restricted the sale of the device to only health care providers that provide a “Patient-Doctor Discussion Checklist-Acceptance of Risk and Informed Decision Acknowledgment.” According to the order, the FDA mandated that Bayer “immediately” implement the changes, noting that the “FDA plans to enforce these requirements” with applicable “criminal and civil penalties.” We should applaud this decision as it is a step in the right direction. This, however, is not enough.

We need more and we need it now. The product has been removed from the market in every country, except the U.S. It must be removed here as well. The most important thing is no one else is harmed by this device. Patient safety should be the number one priority.

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