Timeline of Key Events:

ABORTION IN OUR WATER

Date	Action	(Likely) Violations & Oversights
November 1995	The *Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements* is published.	The EA fails to consider or address how fetal remains would be disposed of, which is required under the National Environmental Policy Act (NEPA). It likewise fails to ensure approval of the drug as requested would comply with all state and local laws on water pollution, including medical waste disposal laws, as required by the Clean Water Act (CWA).
March 1, 1996	The Population Council submits an Environmental Assessment (EA) to the Food and Drug Administration (FDA) as part of a New Drug Application (NDA) for the abortion pill mifepristone, based on the 1995 guidance.	
1997-98	Following the CFR updates, a new guidance for the Industry on *Environmental Assessment of Human Drug and Biologics Applications* is published.	The FDA refers to these guidances seemingly as a means to support the notion that it adhered to the law when approving mifepristone in 2000, finding no further environmental study was required—yet even if the guidance was adhered to, the guidance should not permit violations of the law they are meant to provide guidance on.
2000	The FDA approves the Population Council's NDA for Mifeprex, based on a biased and incomplete Environmental Assessment.	The Clean Water Act outlines that each agency (e.g. the FDA) *"engaged in any activity resulting, or which may result, in the discharge or runoff of pollutants, [e.g. drug approvals] . . . shall be subject to, and comply with, all Federal, State, interstate, and local requirements, administrative authority, and process and sanctions respecting the control and abatement of water pollution*." The National Environmental Policy Act states agencies (e.g. the FDA) shall *"identify and develop methods and procedures . . . which will ensure that presently* ***unquantified environmental amenities and values*** *may be given appropriate consideration in decision making along with economic and technical considerations."* Based on the plain meaning of the CWA and NEPA, the FDA should have ensured approval of the abortion pill would comply with relevant state laws and given "appropriate consideration" to "unquantified environmental values"—in this case, the value of an environment free from contamination by fetal remains—during its original approval of mifepristone. It failed to do so.

2011	The FDA approves a Supplemental New Drug Application (sNDA) for mifepristone that outlined a Risk Evaluation Mitigation Strategy (REMS). While three in-person visits were required, women were still permitted to expel their pregnancy at home.	
2016	The FDA approves a Supplemental New Drug Application (sNDA) for Mifepristone that outlines changes to the REMS which include extending its use from 7 to 10 weeks (70 days), increasing both the overall amount of fetal remains that may enter our sewer systems, and the individual weight of each set of remains. It also removed two of the three required in-person visits.	As outlined in section 4332 and 4336 of the NEPA, ***"every** recommendation or report on proposals for . . . **major Federal actions significantly affecting the quality of the human environment,"*** **require at least an EA,** unless exclusions apply. According the NEPA, "the term 'major Federal action' means an action that the agency carrying out such action determines is subject to substantial Federal control and responsibility." In other words: all supplemental and abbreviated drug applications (instituting and changing REMS as well as approving a generic version of mifepristone) constitute "major federal actions," as would the decision not to enforce the in-person dispensing requirement. No exclusions should have applied, yet no EAs were completed.
2019	FDA approves an Abbreviated New Drug Application (ANDA) for generic mifepristone, failing again to consider the reality that a generic pill would likely increase access to the abortion pill, thereby increasing the amount of fetal remains that would be disposed of. (And even if it did not, it is still a major action requiring an EA.)	
2021	The FDA approves another Supplemental New Drug Application (sNDA) for mifepristone that outlines minor changes to the REMS document/inclusion of gender-neutral language. Also in 2021, the FDA announced that during the COVID-19 emergency, it would "exercise enforcement discretion with respect to the in-person dispensing requirement." This more than likely increased the pill's use as it was determined it can be mailed to women (violating the Comstock Act).	
2023	The FDA approves a Supplemental New Drug Application (sNDA) for mifepristone that outlines changes to the REMS, permanently removing the one remaining in-person visit.	

For more information, visit:
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