Citizen Petition

December 13, 2022

The undersigned submits this petition under 21 C.F.R. § 10.30 and Section 505-1 of the Food Drug and Cosmetic Act (21 U.S.C. § 355-1) to request the Commissioner of the Food and Drug Administration (FDA) to modify the Risk Evaluation and Mitigation Strategy (REMS) regarding mifepristone (Mifeprex® or RU-486) (hereinafter, "Mifepristone") and restore the REMS regarding Mifepristone, that were curtailed in 2016 and 2021, back to the REMS that were formally enacted in 2011.

A. ACTION REQUESTED

This Petition makes one request. We request that the 2021 and 2016 modifications to mifepristone's REMS be reversed and the REMS as they were in 2011 be restored.

Reverse the 2021 and 2016 Mifepristone REMS modification and restore the REMS as they were in 2011.

The REMS for Mifepristone were modified by the FDA in 2021 and 2016. This petition requests that the FDA reverse this modification by requiring that:

1) Mifepristone only be administered, in a regimen with misoprostol, for the termination of intrauterine pregnancy, for up to 49 days (7 weeks) gestation;

2) Mifepristone only be administered by or under the supervision of a physically present physician (to reduce instances of telehealth prescriptions to only those that are absolutely necessary);

3) the use of Mifepristone and misoprostol for the termination of pregnancy necessitate three office visits by the patient: the first to be an ultrasound to rule out ectopic pregnancy, determine the gestational age of the child, to determine if the patient is Rh-negative, and to actually issue Mifepristone. The second, to determine that the termination has been successful, and to make sure that there are no remaining tissues in the body that could lead to infection. The third, as a follow-up to make sure there are no further complications;

Additionally, Mifepristone should be administered only after ectopic pregnancy has been ruled out, and the gestational age of the fetus has been determined. Mifepristone use should be contraindicated for patients who do not have convenient access to emergency medical care. This use should be as limited as possible. Telehealth should not be an option to all women, but only to women in absolute need under extreme circumstances that would make access to a medical care facility impracticable, with a substantial risk that the woman would die without immediate administration of Mifepristone.

To alter the Mifepristone REMS, a formal study should be required. This study should include outcomes for at-risk populations, patients under the age of 18, patients with repeat

Mifepristone abortions, patients who have limited access to emergency room services, patients who self-administer misoprostol, patients who did not have an ultrasound to rule out ectopic pregnancy, patients who did not have an ultrasound to determine the gestational age of the fetus, patients who were prescribed Mifepristone over telehealth, and patients who did not see a physician before or after Mifepristone was administered over telehealth.

Reinstituting the limiting of dispensing of Mifepristone to patients in clinics, medical offices, and hospitals, by or under the physical supervision of a certified prescriber and only up to 49 days (7 weeks) gestation can only benefit women's health. The 2021 and 2016 modifications promulgated by the FDA claimed that the data supported modification of the REMS to reduce the burden on patient access and the health care delivery systems and that the overall benefits of the product outweighed the risks. The modifications to the Mifepristone REMS program should be reversed, reinstituting the requirement that mifepristone be dispensed only in certain health care settings, specifically clinics, medical offices, and hospitals (referred to as the "in-person dispensing requirement"); adding a requirement that pharmacies that dispense the drug be certified; requiring three office visits along with prescription; and only prescribing up to 49 days (7 weeks) gestation. The petitioner requests that the FDA revoke these changes as these modifications are detrimental to the health and safety of women seeking abortions.

B. STATEMENT OF GROUNDS

The FDA should restore and strengthen elements of the Mifepristone regimen and prescriber requirements approved in 2016 and 2021. Mifepristone should be prescribed only up to 49 days (7 weeks) gestation and administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy. Mifepristone should only be prescribed by a physically present physician, and telehealth dispensing should be limited to patients with no other legitimate option.

Mifepristone should only be administered, in a regimen with misoprostol, for the termination of intrauterine pregnancy, for up to 49 days (7 weeks) gestation.

In 2016, FDA increased the maximum gestational age for Mifeprex use for abortion from 49 days (7 weeks) to 70 days (10 weeks), and changed the method of administration of misoprostol from oral to buccal (*i.e.*, in the cheek pouch). However, drug-induced abortion[1] regimens demonstrate an increase in complications and failures after 49 days' gestation.

In a 2011 study of thousands of patients, the majority of whom had a drug-induced abortion using what is now the Mifeprex regimen, the rate of infection and the rate of failure requiring surgical intervention increased with gestational age.[2] The American College of Obstetricians

[1] The terms "Medication abortion," "medical abortion," "chemical abortion," and "drug-induced abortion" [or termination of pregnancy] share the same meaning and refer to the use of abortion-inducing drugs, rather than surgery, to induce abortion. The current FDA-approved regimen uses two drugs, mifepristone (a.k.a. Mifeprex or RU-486) and misoprostol.

[2] Mentula MJ, Niinimaki M, Suhonen S, Hemminki E, Gissler M, and Heinkinheimo O, *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study,* Human Reproduction 26(4), 927-932 (2011).

and Gynecologists (ACOG) has stated: "the risk of clinically significant bleeding and transfusion may be lower in women who undergo medical abortion of gestations up to 49 days compared with those who undergo medical abortion of gestations of more than 49 days."[3]

Further, a 2015 meta-analysis examined all the existing publications on buccal administration of misoprostol, 20 studies in all, from November 2005 through January 2015. The failure rate of the buccal misoprostol regimen increased as the gestational age increased, especially at gestational ages greater than 49 days.[4] The current FDA label also acknowledges this fact.[5]

Given the serious risks of failure, hemorrhage, infection, and ongoing pregnancy that increase as pregnancy advances, the gestational limit for the Mifeprex regimen should have never been increased, and now should be restored back to 49 days (7 weeks).

Mifepristone should be administered by or under the supervision of a physically present certified physician who has ruled out ectopic pregnancy and Rh negativity.

The 2000 Mifepristone regimen required Mifepristone to be "provided by or under the supervision of a physician" who meets qualifications discussed in this section below.[6] However, the 2016 regimen replaced "physician" with "healthcare provider," thus permitting non-physicians to apply to be certified prescribers.[7] Given the regimen's serious risks, the FDA should limit the ability to prescribe and dispense Mifepristone to qualified, licensed physicians. Physicians are better trained to diagnose patients who have contraindications to Mifepristone and to verify gestational age.

In the Mifepristone label, the FDA emphasizes that "Mifepristone is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)" because of the drug's "risks of serious complications." In a bold-print box, the FDA states that before prescribing Mifepristone, a provider must inform a patient: about the risks of serious events; whom to call and what to do if certain symptoms occur; and to take the Medication Guide with her if she visits an emergency room or healthcare provider who did not prescribe Mifepristone, so that she receives appropriate, informed care.[8]

Chemical abortions were first approved by the FDA on September 28, 2000. A chemical abortion, also known as a medical abortion, is a two-step regime. The first is taking RU-486, a synthetic steroid also known as mifepristone. This drug cuts off the production of progesterone in the woman's body, effectively starving the fetus. The second step requires taking misoprostol. This drug then expels the fetus from the woman's body. This drug was initially created to treat

[3] ACOG Practice Bulletin 143: Medical Management of First-Trimester Abortion, p. 5 (Mar. 2014, reaffirmed 2016).
[4] Chen MJ, Creinin MD, *Mifepristone with Buccal Misoprostol for Medical Abortion*, Obstet. Gynecol 126 (1) July 2015 12-21.
[5] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[6] Mifeprex 2000 label, Dosage and Administration, emphasis added.
[7] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[8] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

stomach ulcers. Importantly, the FDA rarely promotes off label uses of medications. Misoprostol has never been approved by the FDA as an abortifacient.

When the FDA approved chemicals abortions, it did so under an accelerated process for drug approval under 21 C.F.R. § 314(H). Before chemical abortions were approved, this approval process had only been used on 30 drugs, all of which were for HIV/AIDS, cancer, and other debilitating diseases. Because chemical abortions were approved under this method, it did not have to go through testing for long-term effects that other drugs have to. This raises red flags as this drug could potentially cause more serious adverse side effects to women.

There was a small trial in the U.S. before this was approved. Clinical trials were conducted on 2,121 women from September 1994 to September 1995 at 17 abortion facilities. The Population Council and the New England Journal of Medicine reported that the most frequent side effect was bleeding and cramping; 56 women underwent surgical intervention for excessive bleeding; four women received blood transfusions; the average duration of bleeding and spotting was 13 days; gastrointestinal side effects of the drugs, such as nausea, diarrhea, and vomiting were documented; eight percent of women did not abort with the medication and were encouraged to have a surgical abortion; and five percent of the women never completed the study.[9]

On the FDA's website the side effects for a chemical abortion are stated as: "cramping and vaginal bleeding are expected effects of the treatment regimen. In some cases, very heavy vaginal bleeding will need to be stopped by surgical procedure, which can often be performed in a healthcare providers office. Other common side effects of the treatment regimen include nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness in the first day or two after taking the two medicines." Still to this day, we don't know if there are any long-term effects on women who opt for a chemical abortion even though it has been over 22 years since initial approval. The medication that is used to complete chemical abortions had not changed since introduction in 2000. However, the guidelines promulgated for its safe consumption have continually been diminished.

The FDA revisions imposed in 2021 permit mail-order telehealth abortions. This runs in contravention to the doctor's code of ethics which requires doctors to examine patients in person at least once before giving them medication with potentially life-threatening side effects. Now women can procure Mifepristone without medical guidance or oversight that would otherwise verify the gestation of the child. This is relevant to know if the chemical abortion will even be effective, to test for Rh negativity, to rule out ectopic pregnancies, and it makes it next to impossible to track the side effects of the chemical abortions.

The 2016 Mifepristone REMS provided that "Mifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber."[10] Many providers today are promoting and performing

[9] Irving M. Spitz et al. *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, New England Journal of Medicine 338, no. 18 (1998): 1241-1247.
[10] Mifeprex 2016 REMS, emphasis added, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2016-03-29_REMS_full.pdf.

"telemedicine abortions," where the certified prescriber's "supervision" of the dispensing of Mifepristone is limited to a videoconference.[11] This practice demonstrates a flagrant disregard for FDA safeguards.

To ensure true supervision, the FDA should require certified prescribers to be physically present when Mifepristone is dispensed so that they can appropriately examine patients and rule out contraindications to the use of Mifepristone. This requirement would be consistent with other requirements in the Mifepristone Label and REMS.

In reality, a de-emphasis on follow-up care increases risks of post-abortion complications. Mifepristone's regimen in 2000 required that women return approximately 14 days after ingesting mifepristone. This was considered necessary to ensure that all pregnancy tissue had been passed.[12] This determination is crucial, because retained pregnancy tissue can lead to continued bleeding and serious intrauterine infections. The return visit permits healthcare providers to ensure that a patient is not experiencing these or other complications from the abortion procedure, and that Rh negative patients are administered Rhogam to protect future pregnancies.

Abortion advocates argue that three clinic visits make accessing abortion-inducing drugs more difficult for patients with transportation challenges; however, ACOG acknowledges that drug-induced abortion is contraindicated for patients who "are not available for follow-up contact or evaluation."[13] Surgical abortion is a better choice for these patients, because it "[d]oes not require follow-up in most cases."[14]

Drug-induced abortion is optional. If a woman does not meet the criteria necessary to use abortion-inducing drugs, then surgical abortion is still an option. For women with transportation difficulties, an abortion provider can complete surgical abortion "in a predictable period of time," and the procedure "[d]oes not require follow-up in most cases."[15]

Efforts to promote abortion-inducing drugs to women in rural areas where access to emergency medical care is scarce are detrimental to women's health. It is better for a patient in a remote region to have a surgical abortion, "which requires a single visit, and is less likely to result in serious or life-threatening complications."[16]

In the Mifepristone label, the FDA emphasizes that "Mifepristone is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)" because of the drug's "risks of serious complications." In a bold-print box, the FDA states that before prescribing

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[11] See Planned Parenthood Releases New Educational Video on Telemedicine Abortion (Feb. 6, 2018), https://www.plannedparenthood.org/about-us/newsroom/press-releases/planned-parenthood-releases-new-educational-video-on-telemedicine-abortion.
[12] Mifeprex 2000 label, Day 14: Post-Treatment Examination.
[13] ACOG Practice Bulletin 143, p. 6.
[14] *Id*.
[15] ACOG Practice Bulletin 143, p. 3 & Box 1.
[16] Donna Harrison, M.D. & Michael J. Norton Testimony before the Iowa Board of Medicine, p. 9 (Aug. 21, 2013), citing Postmarket Drug Safety Information for Patients and Providers, Questions and Answers on Mifeprex, https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm492705.htm.

Mifepristone, a provider must inform a patient: about the risks of serious events; whom to call and what to do if certain symptoms occur; and to take the Medication Guide with her if she visits an emergency room or healthcare provider who did not prescribe Mifepristone, so that she receives appropriate, informed care.[17]

Thirty-four states permit only physicians to prescribe Mifepristone,[18] with nineteen states requiring the provider to be physically present with the patient.[19] For example, the law in Alabama states that the physical presence and care of a physician are necessary because "the failure and complications from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies."[20]

Lawmakers in these states recognize that abortion providers cannot diagnose contraindications and cannot adequately care for their patients through a videoconference. Fundamentally, telemedicine "may be legitimate when it comes to discrete, document-based tasks such as reading X-rays," but it "is not the standard of care when it comes to abortion or the management of miscarriage."[21]

The 2016 regimen significantly diminished doctor-patient interaction. While the 2000 Mifeprex label required three patient visits with the abortion provider, women may now obtain Mifeprex at a clinic and self-administer it at home. They are no longer required to return to the clinic for the administration of misoprostol, which prevents abortion providers from ensuring that they take the drugs at the correct times. Further, providers may now "confirm" that a patient's drug-induced abortion was successful without a clinic visit,[26] increasing the possibility that Rh-negative patients will not receive administration of Rhogam, which is necessary to prevent serious risks in subsequent pregnancies. The failure to test for Rh-negativity could lead to infertility.

The 2016 regimen directs that patients be given or prescribed misoprostol to take 24 to 48 hours after taking Mifeprex. However, without monitoring, a patient may take misoprostol before 24 hours have passed since she consumed Mifeprex, rendering the regimen ineffective and increasing the likelihood that she will experience a failed drug- induced abortion and require surgery.

Using buccal misoprostol sooner than 24 hours after administering mifepristone leads to a significantly increased failure rate. In one study investigating the timing of buccal misoprostol after Mifepristone, nearly one out of every three to four women who took buccal misoprostol

[17] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[18] Donovan MK, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, Guttmacher Policy Review, Vol. 21, p. 44 (2018).
[19] *Id.*
[20] Ala. Code § 26-23E-7.
[21] Harrison & Norton Testimony, p. 3.

shortly after Mifepristone failed to abort.[22] The failure rate ranged from 27% to 31%, depending on the pregnancy gestation.[23] Given these results, the authors of this study strongly recommended that buccal misoprostol not be taken immediately after Mifepristone because of the very high abortion failure rate.[24] However, with home administration of misoprostol, healthcare providers have no control over when their patients consume the drug.

A woman may also choose to swallow misoprostol rather than keep the pill between her cheek and gum for 30 minutes, converting a "buccal" administration into an "oral" administration. An oral administration of misoprostol following the lower dose of Mifepristone in the current regimen is not as effective in ending the pregnancy.

Further, waiting until 24 hours after Mifepristone to administer misoprostol does not guarantee success, and the failure rate of buccal misoprostol is higher than that under the 2000 regimen. A comprehensive systematic review and meta-analysis of the existing studies of the 2016 regimen found that women who take misoprostol earlier than 48 hours after Mifepristone are more likely to fail the regimen.[25]

Under the 2000 regimen, doctors were also able to provide care to patients during the most challenging and painful time in the drug-induced abortion. According to the World Health Organization, up to 90% of women will abort within 4-6 hours after taking misoprostol.[26] The 2000 regimen permitted a patient to be in a clinic for this period of time, during which she would be under the observation and care of medical personnel. This observation period is for "both patient safety and compassion. This is the time when women should be in a place where their bleeding can be monitored, their vital signs can be observed by trained medical personnel, and they can receive sufficient pain medication during the most difficult part of the expulsion."[27]

In-person contact with a healthcare provider is critical to post-abortion care as well. Abortion providers should perform a "follow-up [physical exam] after the use of mifepristone in order to confirm abortion and rule out life-threatening infection."[28] Before the FDA approved the 2016 regimen, the follow-up visit was considered "very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred."[29] In fact, the 2000 label provided that "[e]ach patient must understand the necessity of completing the treatment schedule, including a follow-up visit approximately 14 days after taking

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[22] Lohr PA, Reeves MF, Hayes JL, Harwood B, Creinin MD, *Oral Mifepristone and buccal misoprostol administered simultaneously for abortion: a pilot study*, Contraception 76 (2007) 215-220.
[23] *Id.*
[24] *Id.*
[25] Chen MJ, Creinin MD, *Mifepristone with Buccal Misoprostol for Medical Abortion*, Obstet. Gynecol 126 (1) July 2015 12-21.
[26] World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* 45.
[27] *Okla. Coalition for Reproductive Justice v. Cline*, Case No. CV-2014-1886 (Feb. 24, 2015) ¶ 136.
[28] Harrison & Norton Testimony, p. 18.
[29] Mifeprex 2000 label, Day 14: Post-Treatment Examination.

Mifeprex."[30] ACOG's current policy explains that:

> Women are not good candidates for medical abortion if they … desire quick completion of the abortion process [or] are not available for follow-up contact or evaluation.[31]

In addition to ensuring for all drug-induced abortion patients that the uterus has been emptied of retained tissue and that they are not suffering from infection, the follow-up examination is particularly critical for Rh-negative patients. These patients must be administered Rhogam in order to prevent Rh isoimmunization in subsequent pregnancies. Without follow-up, women will not receive the Rhogam after the abortion, greatly increasing their risk of subsequent Rh isoimmunization, which can endanger future pregnancies.[32]

Nonetheless, abortion advocates strongly supported the reduction in required visits, and continue to advocate for the elimination of direct provider-patient contact. Gynuity Health Projects (an organization that "has been at the forefront of efforts to increase women's access to medical abortion in settings throughout the world")[33] has conducted at least three domestic and five international studies[34] on eliminating pelvic ultrasound or exam after drug-induced abortion. Following one study, researchers determined that "[s]emi-quantitative pregnancy tests … could be used in lieu of transvaginal ultrasound and/or serum hCG at clinic-based follow-up or by women themselves for home-based follow-up."[35] This ignores the risks outlined above.

In a more recent study, researchers asserted that the "common practice of scheduling a clinical contact after every medical abortion may not be necessary to ensure safety; enabling patients to determine for themselves whether or not a contact is needed can be a reasonable approach."[36] They reached this conclusion even with 26% of participants failing to provide

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[30] Mifeprex 2000 label, Information for Patients.
[31] ACOG Practice Bulletin 143, p. 6.
[32] ACOG Practice Bulletin 181: Prevention of Rh D Alloimmunization (Aug. 2017);
and SOGC Clinical Practice Guidelines: Prevention of Rh Alloimmunization (No. 133, Sept. 2003).
[33] See Gynuity Health Projects, Medical Abortion, https://gynuity.org/programs/medical-abortion.
[34] See, e.g., Self-Assessment of Medical Abortion Outcome Using Serial Multi-level Pregnancy Tests [NCT02570204] (Sept. 2015 – Dec. 2016),
https://www.clinicaltrials.gov/ct2/show/NCT02570204?term=Self-Assessment+of+Medical+Abortion+Outcome+Using+Serial+Multi-level+Pregnancy&rank=1; Exploring the Role of At-home Semi-Quantitative Pregnancy Tests for Medical Abortion Follow-up [NCT01150279] (Aug. 2009 – May 2014),
https://www.clinicaltrials.gov/ct2/show/NCT01150279?term=Exploring+the+Role+of+At-home+Semi-Quantitative+Pregnancy+Tests+for+Medical+Abortion+Follow-up&rank=1; De-Medicalizing Mifepristone Medical Abortion [NCT00120224] (May 2005 – Apr. 2007),
https://www.clinicaltrials.gov/ct2/show/NCT00120224?term=De-Medicalizing+Mifepristone+Medical+Abortion&rank=1.
[35] Lynd K, et al., *Simplified Medical Abortion Using a Semi-Quantitative Pregnancy Test for Home-Based Follow-up*, Int J Gynaecol Obstet. 2013 May;121(2):144-8.
[36] Raymond EG, et al., *Self-assessment of Medical Abortion Outcome Using Symptoms and Home Pregnancy Tests,* Contraception *97* (2018) 324-28.

sufficient follow-up information.[37]

Gynuity researchers also conducted a recent systematic review of existing studies on "the accuracy and acceptability of a strategy for identifying ongoing pregnancy after medical abortion treatment using a low-sensitivity pregnancy test (LSPT)." While the researchers acknowledged that "the LSPT strategy had *moderate* sensitivity for identifying ongoing pregnancy" and "the LSPT itself had a limited role in the detection of treatment failures [*i.e.*, ongoing pregnancy] in the studies," they stated that the "LSPT strategy shows promise for reducing the need for in-person follow-up after medical abortion. A range of home-based options should be validated to meet the varied needs of women and abortion providers in diverse settings."[38]

In reality, a de-emphasis on follow-up care increases risks of post-abortion complications. As discussed above, the 2000 regimen's requirement that women return approximately 14 days after ingesting mifepristone was considered necessary to ensure that all pregnancy tissue had been passed.[39] This determination is crucial, because retained pregnancy tissue can lead to continued bleeding and serious intrauterine infections. The return visit permits healthcare providers to ensure that a patient is not experiencing these or other complications from the abortion procedure, and that Rh negative patients are administered Rhogam to protect future pregnancies.

Abortion advocates argue that three clinic visits make accessing abortion-inducing drugs more difficult for patients with transportation challenges; however, as noted above, ACOG acknowledges that drug-induced abortion is *contraindicated* for patients who "are not available for follow-up contact or evaluation."[40] Surgical abortion is a better choice for these patients, because it "[d]oes not require follow-up in most cases."[41]

Drug-induced abortion is a longer process that requires more attention and care from healthcare providers. Three visits to a physician in the interest of patient safety should not be sacrificed for the convenience of healthcare providers or even their patients.

Limit The Dispensing Of Mifepristone Over Telehealth

Mifepristone should be administered by or under the supervision of a physically present and certified physician who has ruled out ectopic pregnancy and instances of administration over telehealth be limited to only those situations where a patient has no clear alternative.

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[37] *Id.*
[38] Raymond EG, et al., *Low-sensitivity Urine Pregnancy Testing to Assess Medical Abortion Outcome: A Systematic Review,* Contraception (2018), https://doi.org/10.1016/j.contraception.2018.03.013 (emphasis added).
[39] Mifeprex 2000 label, Day 14: Post-Treatment Examination.
[40] ACOG Practice Bulletin 143, p. 6.
[41] *Id.*

As mentioned above, the original Mifepristone regimen required Mifepristone to be "provided by or under the supervision of a physician" who meets qualifications discussed in this section below.[42] However, the 2016 regimen replaced "physician" with "healthcare provider," thus permitting non physicians to apply to be certified prescribers.[43] Given the regimen's serious risks, the FDA should limit the ability to prescribe and dispense Mifepristone to qualified, licensed physicians. Physicians are better trained to diagnose patients who have contraindications to Mifepristone and to verify gestational age.

The previous Mifepristone REMS requires that Mifepristone "be dispensed to patients only in clinics, medical offices and hospitals, by or under the supervision of a certified prescriber." That prescriber must be capable of assessing the duration of a pregnancy accurately, diagnosing ectopic pregnancies, and providing or referring for surgical intervention in cases of incomplete abortion or hemorrhaging.[44]

Abortion advocates, however, want prescription of Mifepristone to increase to pregnant patients over the Internet or phone, with the drug available at pharmacies or through the mail, and through advance provision (i.e., before a patient is pregnant). Eliminating and relaxing the REMS to facilitate Internet or telephone prescriptions is dangerous to women and adolescent girls. This must be reversed to ensure the appropriate care for the health of women and adolescent girls. Healthcare providers prescribing abortion-inducing drugs over the Internet or phone or before a patient is even pregnant cannot adequately evaluate patients for contraindications to the drugs. Further, as discussed above, Rh-negative patients must be administered Rhogam in order to prevent Rh isoimmunization in subsequent pregnancies. Without direct patient contact, women will not receive the Rhogam after the abortion, greatly increasing their risk of subsequent Rh isoimmunization, which can endanger future pregnancies and lead to potential infertility.[45]

Telemedicine abortion further distances women from the practitioners responsible for caring for them, and modification of the REMS in 2021 by FDA further absolved abortion providers of responsibility for the well-being of their patients. Promoting telemedicine abortion to women and adolescent girls in rural areas with limited access to healthcare is extremely dangerous—they will have little recourse if they face known and predictable emergency complications such as severe hemorrhage.[46]

Previous Mifepristone REMS, provided that "Mifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, *by or under the supervision of a certified prescriber*."[47] Yet, abortion providers today are increasingly

[42] Mifeprex 2000 label, Dosage and Administration, emphasis added.
[43] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[44] Mifeprex Risk Evaluation and Mitigation Strategy (REMS),
https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2016-03-29_REMS_full.pdf.
[45] ACOG Practice Bulletin 181: Prevention of Rh D Alloimmunization (Aug. 2017);
and SOGC Clinical Practice Guidelines: Prevention of Rh Alloimmunization (No. 133, Sept. 2003).
[46] Harrison & Norton Testimony, p. 9.
[47] Mifeprex 2016 REMS, emphasis added,
https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2016-03-29_REMS_full.pdf.

promoting and performing "telemedicine abortions," where the certified prescriber's "supervision" of the dispensing of Mifepristone is limited to a videoconference. This practice demonstrates a flagrant disregard for FDA safeguards.

In allowing this disconnect between patients and prescribers, the FDA is creating circumstances that could lead to patient abandonment. According to the National Library of Medicine, patient abandonment "is considered a breach of duty and is defined as unilateral termination of the physician-patient relationship without providing adequate notice for the patient to obtain substitute medical care."[48] Further, the "patient-physician relationship becomes established when a physician affirmatively acts in a patient's care through the patient's diagnosis and/or treatment. This relationship is also established if the physician agrees to diagnose and/or treat the patient. A physician-patient relationship is often created when the "professional services of a physician are rendered to and accepted by another person for the purposes of medical or surgical treatment."[49] By definition then, the prescribing of Mifepristone by a medical provider to a patient establishes a physician-patient relationship. The level of care implicit in this relationship is thus abrogated in an unacceptable way when the prescription of Mifepristone is conducted solely via telehealth.

To ensure true supervision, the FDA should require certified prescribers to be physically present when Mifepristone is dispensed so that they can appropriately examine patients and rule out contraindications to the use of Mifepristone. This requirement would be consistent with other requirements in the Mifepristone label and REMS. In some situations, it is possible that a woman may *not* take the abortion drugs in the manner prescribed, nor obtain the follow-up care that is recommended. With a doctor-patient relationship limited to online chats, she has virtually no accountability or support as she navigates a complicated procedure. The responsibility of the provider of the drugs to follow up with the patient is obviated as well.

In the Mifepristone label, the FDA emphasizes that "Mifepristone is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)" because of the drug's "risks of serious complications." In a bold-print box, the FDA states that before prescribing Mifepristone, a provider must inform a patient: about the risks of serious events; whom to call and what to do if certain symptoms occur; and to take the Medication Guide with her if she visits an emergency room or healthcare provider who did not prescribe Mifepristone, so that she receives appropriate, informed care.[50]

A provider who does not physically meet with and examine a patient, but simply consults with the patient over the Internet, is not capable of fulfilling these requirements, or of ruling out additional contraindications (i.e., circumstances that make a treatment or medication *unadvisable*) to Mifepristone use. These physical contraindications include pelvic infections, ovarian masses, cardiac arrhythmias, and liver abnormalities.[51] A physician bears responsibility to diagnose and rule out contraindications prior to Mifepristone use. It is inadequate to entrust this critical care to another healthcare provider who is not trained in diagnosis. Further, a healthcare provider who is

[48] https://www.ncbi.nlm.nih.gov/books/NBK563285/.
[49] *Id*.
[50] Mifeprex 2016 label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[51] Harrison & Norton, p. 3.

not physically accessible to a patient cannot provide adequate follow-up care to patients, as required by the FDA Mifepristone regimen.

Abortion complications are also more frequent when women abort at home, without the oversight of a healthcare provider. A 2018 combined retrospective and longitudinal follow-up study of complications related to induced abortion in Sweden determined that "[t]he complication frequency [of drug-induced abortion] was significantly higher among women <7 gestational weeks who had their abortions *at home*."[52]

The 2000 Mifeprex label stated:

> Because it is important to have access to appropriate medical care if an emergency develops, the treatment procedure is contraindicated if a patient does not have adequate access to medical facilities equipped to provide emergency treatment of incomplete abortion, blood transfusions, and emergency resuscitation during the period from the first visit until discharged by the administering physician.[53]

This critical language was excluded from the 2016 Mifeprex label. Yet, studies comparing the outcome of surgical versus drug-induced abortion have clearly demonstrated that Mifeprex abortions have a greater risk of hemorrhage, infection, continued pregnancies, retained tissue and need for emergency reoperation than surgical abortions. ACOG acknowledges that "[c]ompared with surgical abortion, medical abortion takes longer to complete, requires more active patient participation, and is associated with higher reported rates of bleeding and cramping," and has lower success rates.[54]

The FDA, in "Questions and Answers on Mifeprex" categorizes women who should not take Mifeprex, specifically the agency states:

> A woman should not take Mifeprex if it has been more than 70 days since the first day of her last menstrual period, or if she: has an ectopic pregnancy (a pregnancy outside of the uterus) has problems with the adrenal glands (the glands near the kidneys) is currently being treated with long-term corticosteroid therapy (medications) has had an allergic reaction to mifepristone, misoprostol or similar drugs has bleeding problems or is taking anticoagulant (blood thinning) drug products has inherited porphyria has an intrauterine device (IUD)

[52] Carlsson I, Breding K, and Larsson PG, *Complications Related to Induced Abortion: a Combined Retrospective and Longitudinal Follow-up Study*, BMC Women's Health (2018) 18:158, p. 4 (emphasis added).
[53] Mifeprex 2000 label, Contraindications.
[54] ACOG Practice Bulletin 143, p. 3 & Box 1.

in place (it must be removed before taking Mifeprex).[55]

And yet, with the proliferation of telehealth prescription, it is less and less likely that the prescribing "healthcare provider" will have first-hand knowledge that the patient will not have these complications or is otherwise less able to the tests necessary to rule out any of these complications.

Drug-induced abortion is optional. If a woman does not meet the criteria necessary to use abortion-inducing drugs, then surgical abortion is still an option. For women with transportation difficulties, an abortion provider can complete surgical abortion "in a predictable period of time," and the procedure "[d]oes not require follow-up in most cases."[56]

Efforts to promote abortion-inducing drugs to women in rural areas where access to emergency medical care is scarce are detrimental to women's health. It is better for a patient in a remote region to have a surgical abortion, which requires a single visit, and is less likely to result in serious or life-threatening complications.

CONCLUSION

Mifepristone carries risks of life-threatening hemorrhage, infection, continued pregnancy, retained tissue, need for emergency surgery, and death. The 2011 regimen provided significantly more protections for patients than the 2016 regimen or the 2021 regimen. FDA should restore and strengthen elements of the Mifepristone regimen and provider requirements, including: limiting Mifeprex use to 49 days' (7 weeks) gestation; requiring that Mifepristone be administered only by or under the supervision of a physically present physician; requiring three office visits by a patient who has been prescribed Mifepristone; and clarifying that Mifepristone use is contraindicated for patients who do not have convenient access to emergency medical care. The agency should restore the original Mifepristone REMS, and return to limiting the dispensing of Mifepristone to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.

C. ENVIRONMENTAL IMPACT

Petitioner is categorically excluded from conducting an environmental impact statement under 21 C.F.R. § 25.30, 25.31, 25.32, 25.33, or § 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

D. ECONOMIC IMPACT

Petitioner will submit information upon request of the Commissioner following review of this petition.

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[55] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex

[56] ACOG Practice Bulletin 143, p. 3 & Box 1.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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Harley	Vance
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Ernest	King
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Steven	Barker
Gianna	Faddis
Am	Atkins
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Tani	Valentine
Brenda	Penta
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Lorrie	Stubitsch
Caleb	Sprenkle
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Susan	Johannes
Andy	Marsee
Lisa	Marsee
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Anthony	Poidmore
Allyson	Atkins
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Ashley	Earnest
Janice	Freeman
Thomas	Belcher
Ben	Daniels
William	Blaty
Pauline	Daniel
Cheryl	Milton
Cynthia	Stone
Christian	Blackburn
Alyce	Sarsi
Dana	FRANCK
Dave	Inocente
David	Mazzocco
Dean	Menezes
Geraldine	TREVASKIS
Damien	Murphy
Damien	Murphy
Don	Henson
Don	Farland
Ellen	Easum
Eugene	Monteilh
Joann	veenstra
Frances	Giardinelli
Finley	Vigil
Gabrielle	Pereria

Gayla	Citizen Young
Georgia	Ladd
Gabriel	Gottheim
Tracy	Gordon
Thomas	Shimada
Tom	Hallsten
Holly	Dane
Margaret	Hinchliff
Renee	Iovino
Irma	Michel
Jacqueline	O'Lea
Jane	Lemmons
Jasmin	Orozco
Debbie	Jackson
Joe	DeLeon
Joshua	Hammer
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Karen	Gonzalez
Karol	Delmar
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Merijule	Washington
Martha	Jenkins
Megan	Erickson
Matthew	Clark
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Marie	T Trew
Rosemary	Mullane
Nellie	Jorge
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Oscar	Vazquez
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Teresa	Marsano
Patricia	Burke
Penelope	S
Racheal	Yard
Rachel	Buckman
Richard	Verdugo
Margaret	Rodriguez
Roger	W Pearson
Shelley	Maloney
Shirley	DeLeon
Silvestre	Luna
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Vincent	Desbieys
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Pearl	Homiak
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Jack	Hood
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Christopher	Kirkman
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Liz	Clark
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Mia	Akins
Marian	James
Michael	Madia jr

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Rachel	hope
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Roy	Cochran
Rosemary	Erickson
Raul	Delgado
Terry	Norman
Stephana	Joseph
Susanne	I Odena
Susan	Thomas
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Tessa	Charlot
Randy	Iosua
Tzirl	reznik
Vikki	Delgado
Wilma	Wissbroecker
Yebrail	Brennan
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Mary	Mccarthy
Dennis	Phipps
Joanne	Kennedy
Marianne	B Ball
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Stacy	Moreira
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Alexander	Akins
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Charlton	D Todd
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Regina	Ceisel
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Ray	Schultz

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Sarah	Gray
Susan	kron
Susan	Gomez
Angelo	Sturino
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Kathleen	Hahn
Diane	Schlueter
Randall	Harris
Anna	Hoff
Alex	Yarbor
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Mike	Gossman
Kaitlynn	Perry
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Jean	Knarr
Jeremy	Lung
James	Walters
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Sister	Marcene
Stephen	Reen
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Elliette	Hasner
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Rodrigo	Fernandez
Julie	Dodson
Erika	Steip
Gabrielle	Pritchett
Ana	Rumback
Linda	Andalikiewicz
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Deon	Durst
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Sr.	Mary Ellen
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Margo	Otterstetter
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Susan	Carson
Scott	Pavlik
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Eden	Logan
Christina	Hudson
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Linda	Hoeck
Lindsay	Rupprecht
Mary	A Cole
Martin	Croxton
Michael	Mendelsohn
Mike	Fernando
Gary	Sabel
Therese	Ruesink
Tom	Leonard
Denis	Hinz
Joan	Bayer-Smith
Pamela	Clark
Dennis	Arbour
Bonnie	Hackett
Laura	Gallic
Gary	Bestwick
Abby	Jones
Angela	Lazzarino
Anna	Mason
Arend	Gilligan
Antal	Family
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Barbara	L. Kelley
Christen	Burman
Lacy	Comstock
Catherine	Snow
Dan	Brodersen
Dan	Richardson
Dennis	BENSTEAD
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Hallie	Smith
James	Robinson
Julie	Llewellyn

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Ken	Themm
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Maria	Haley
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Tal	Sullivan
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Leah	Anderson
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James	Mooney
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John	Jalanivich
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Suzanne	Harris
Bailey	Throness
Gwen	Cloninger
Pat	Bollinger
Sarah	Evans
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Annette	Powell
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Bryon	Sundberg
Ruth	Harbin
Bradley	Smith
Jessica	Stephens
Darrell	Rader

Daniel	Agemy
Hannah	Ruesch
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Ruth	Bennett
Khalilah	Ballard
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Charlotte	Oliver
Jeff	Mathews
Annette	DesJardins
Norine	Carter
Rebecca	Hughes
Patricia	Warren
Kathleen	Breen
Ross	Dunn
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Wes	weaver
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Joseph	Gartner
Sharla	Meyer
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Lauren	J. Whitcomb
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Jeannie	Thompson
Jack	Preston
Colleen	thomas
Ken	Smitelli
Joan	Mullaney
Willem	Siek
Althea	Ansah
Daniel	Birck
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Thomas	Witham
Alison	Morrison
Alex	Rubens
Anita	Mercanti
Bonnie	Cooper
Carole	Hasz
Cliff	Jones
Colletta	Liccardi
Diane	DiGiovacchino
Rosemarie	Colon
Elsabe	Combrink
Frank	Cestone
Elizabeth	Arias
Renato	N. Gadenz
Gerard	H. McCarren
George	J. Muench
Barbara	Joyce Antone
Luz	Morales
Nataly	Gaspar
Robert	Rypkema
Scott	Fenton
Zbigniew	Sutor
David	Brandt
Julia	Watry
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Kathleen	Sifuentes
Simon	Spence
Tom	Goodwin
Dana	Aragon
Judy	EDWARDS
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Alice	Zelenak
David	Sonner
Amanda	Graham
Ed	Simmons
Sue	K Boda
Gregory	Dunn
Katy	McPherson
Crissi	Kendall
Ron	Kalcso
Karen	Russo
Angela	Salerno
Anthony	O'Connor
Doug	Arters
Alfonso	Oliveras
Candace	Smith
April	Penny
Ashley	O'Neill
Barbara	Jacobini
Joanna	Louise Johnson
Carol	Brodie
Judith	Johnson
Christina	Strickland
Deborah	Cochrane
Colleen	Kelly Spellecy
Donna	Washio
Elsa	Caputi
Margo	Romney
Kenneth	Breen
Joy	Goldberg
James	Robert
Kenneth	Grek
Kimberly	Roberts
Leonard	EDWIN

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Lawrence	Petry
Margaret	Colindeas
Trevor	MERCHANT
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Olivia	Cunningham
Dee	Shatalow
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Robert	Abarno
Robert	James Kaufmann
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Braelynn	Roach
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Mike	Drummond
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Frederick	Schieltz
Anna	Graham
Gail	Wetzel
Corinne	D'Abreau
Heather	Cogan
Karen	Spremulli
Jennifer	Lapos
Joan	R. Martinez
Jeanine	Arrigo
Joan	Nunnery
Judy	Brickels
Karen	Rizzo
Kathy	Tscheiner
Kevin	Barber

Kathryn	McNutt
Karah	Enders
Laura	Benge
Cathy	McCarthy
Janet	Maag
Ann	Warnecke
Mark	Tomecko
Mary	Rizzo
Joyce	Thomas
Khristina	Kisner
Alana	Noe
Mark	E. Tebbe
Mary	Adler
Rob	Polans
Patricia	L. Peterson
Barbara	Smith
Patricia	Morwood
Renee	Szabo
Shirley	Stryffeler
Patricia	Spath-Meyer
Steve	Powers
Ruth	Messsbarger
Amanda	Patalune
Teresa	Trese
Tom	Fumich
John	Heidenreich
Jennifer	Wolfe
George	Wolph
Barbara	Zupcsan
Zoe	Wilson
Madison	Vanbuskirk
Brenna	Thiessen
Ilyssa	Freiburger
Judith	McCalla
James	Dooley, Sr.
Jerrie	Yoakam
Angela	Stapp
Donna	Kay Curtis
Donita	Cooper
Edgar	Gaytan

Elain	Hedrick
Gracie	Gross
Anada	Haas
Dennis	Jackson
Jennifer	Arnove
Kathi	Andrews
Terry	Largent
Stephen	Burke
Marsha	Yancey
Merlinda	Tate
Joanna	Toombs
Sharin	Burke
Thomas	Galanos
Jennifer	LeBlanc
Aaron	Crook
Robert	Paeth
Brandi	Jacobs
Doug	Gibson
Edward	lattanzi
Gordon	Murphy
Gordon	Wavra
Mary	Nordlund
Miriam	Plato
Noel	Fernandis
Rita	Stancik
Roger	Maurer
Sheryl	Beasley
Tom	Kirsch
John	Lautenschlager
Anna	M. Dushole
Arlene	L. Binner
Anita	Schragen
Bella	Croton
Philip	Plank
Isobel	Dozier
Mary	Leitem
Carol	A. O'Donnell
Lindsey	Jauregui
Catherine	Baker
Cecelia	Farabaugh

Cindi	Andersen
Cara	Meskill
David	Clark
Mary	Kathleen Skalka
Elizabeth	A. Veres
Eric	Yablonski
Lucia	Fiorini
Patricia	Dewing
Frank	Schell
Genevieve	LaFosse
Geri	A. Fisher
Ginny	Crapser
Barbara	Smith
Dylan	Hammer
Krisi	Keley
Joseph	DeVizia
James	Alfano
Donald	Bruner
Katherine	Burkholder
Kenneth	Buckley
Keri	Muir
Dave	Kozemchak
James	Carr
Larry	Fleming
Madeline	O'Brien
Dave	Mattozzi
Margaret	Chapman
Martin	Eagan
Phillip	Ettelschutz
Mary	Elizabeth Schlenker
Millie	Gondek
Michael	Whitson
Kathleen	Connelly
Mary	Grace Schmitt
Leticia	Hagstrom
David	Morgan
Linda	Ritchie
Daniel	R. Natt
Karen	W. Natt
Paul	Celentano

Peter	Moskowitz
Dennis	Ramsey
Richard	Hammer
Richard	Keyser
Larissa	Shapren
Bob	Schneider
Ronald	Frederico
Linda	Peffer
Barbara	Rose
Samantha	Barr
Thomas	Allen Schwartz
Felix	Alray
Susan	Misa
Stephen	Gorbos
Shirl	Assal
Frank	P. Barrella
Alvin	Ratliffe
Ed	Kordick
Terezia	Lazorik
Thomas	Barrage
Christine	Junker
Anthony	Miller
Watson	J. Olszewski
Melissa	Hammer
Jan	Kuehlich
David	L. Peters Jr
Jena	Lewis
Michael	PHILLIPS
Shannon	Harsh
David	Lelli
Donald	Solomo
Mary	K. Paddenburg
Barbara	McGuigan
Charity	Peck
Dean	K. Clark
Diana	L. Comer
Kinga	Snell
Allen	Hogan
Amy	Shepherd
Joseph	Golob

Karen	Boles
Karen	Franzen
Kylie	Michieli
Lauren	DeLo
Hayden	Laye
Marilyn	Lehman
Nicole	Dan
Susan	Bates
Cathleen	Smith
Cindy	Siebrecht
Christine	Schelske
Dan	McCormick
Dave	Nordlund
Sally	Jones
Sharon	Gray
Joe	Ulin
Jean	Shepard
Kathryn	Asfeld
Joni	Krause
Nancy	Barone
John	Smith
Mark	Brickman
Kristen	Warren
Chris	Johnson
Courtney	Struna
David	N Miller
James	Davis
Daniel	Charles Sherry
Debbie	Masciale
Dorothy	Powell
Ellen	Vigilante
Euclides	Solivan Jr
Freida	Thomas
Gene	Gazzara
Linda	Gray
Sharon	Kurtz
Jack	Thomas Clinton
Jenny	Boyd
Jeffery	Ensley
Junius	Graham

Karen	Dunaway
Kenn	Claude Blankenship
Linda	Love
Elizabeth	Dozier
Joann	P Williamson
Michael	Moore
Mary	horne
Paul	Christopher
Amy	Ritter
Mary	Elizabeth Waugh
A.	Pierce
Maria	Speight
Johnnie	Stephens
Kitty	Parker
Michelle	M Schneider
Kate	McKeehan
Emmafae	Lemons
Keely	Gililland
Isaac	Monteleone
Marjorie	Liedtke
Yesenia	Rodriguez Ruiz
Angela	Lukens
Benjamin	Sell
Alison	Sims
Claire	Hibbs
Donna	Stowell
Erma	Thomas
Matthew	Sprague
Jennifer	Tyler
Joshua	Cruice
John	Puffer
Kris	Ellen Pinckney
Laura	Howard
Lisa	M
Lawrence	Nagle
Betty	Murdock
James	Thomas Putman
Jenna	Dolbare
Sondra	Dayton
Susan	Pomranky

Susan	Sutphin
Samuel	Jason Hooker
Paul-Leon	Tuzeneu
Suzy	Ravitch
Bill	Kilgore
Janice	Breedlove
Anita	Zeiser
Alan	M Becker
Sandra	Munoz
Anna	Simmacher
Olivia	Tamez
April	Morley
Anita	Shirley
Briana	Vasquez
Bryan	Malatesta
Julie	Bush
Carol	Bannerman
Lavinia	Calota
Carla	Smith
Carolyn	McClugage
Claire	Pace
Colleen	Luikart
Dale	johnson
Dennis	Mattli
Jonathon	Delaney
Delia	Tuttlebee
Donna	Hart
Donna	Bogema
Donna	Caster
Erika	Salazar
Elizabeth	Georgette Moreno
Ellie	Contreras
Joy	Gautney
Gaylon	George
Gerry	Brundage
Imelda	Valadez
James	Austin Pinedo
Janis	Hillin
John	J GILLULY
John	Courtney

James	Guillory
Karen	Werner
Joanna	Kennedy
Gary	Kent Boyd Jr
Kaylyn	Madany
Karen	Bingman
Riley	Sisco
Margaret	A Foland
Elizabeth	Moon
Marcy	Bloomfield
Mary	Cashion
Mark	Douglas Nightingale
Melanie	Mattil
Gloria	A Pope
Miles	Bedlan
Mindy	Villegas
Monika	Montecillo
Claire	Mullan
Samantha	Rhodes
Noel	Brinkerhoff
Jerome	ILTIS
Pamela	Littlepage
Peggy Ann	Weesner
David	Porter
Paula	Cordova
Rebekah	David
Dave	Cross
Rita	Cross
Robert	Parlee
Loretta	Bosley
Ramona	Krenek
Ronald	Samek
Richard	Razvillas
Annaliese	Schultz
Lorran	Rodriguez
Stanley	J Sramek
Alex	Alaniz
Adam	McManus
Virginia	Choate
Tommy	Chatlosh

Teresa	Rodriguez
James	Theisen
Tia	Viera
Cristina	Flores
Craig	Vernieu
Gail	Watts
Dorothy	Hussey
Jerusha	Welborn
Lacey	Lofgreen
Tami	Higbee
Linda	Paulson
Reggie	Voyce
Ry	MORAN
Elijah	Hatch
Allyson	Harris
Christine	strasser
Everett	Michael Griffiths
Lacie	Knight
Gene	Dwyer
Gray	Turner
Maryann	Hagan
Vicky	Hepperle
Janice	Towne
Karen	Lahr
Nina	P Newton
Carl	Walker
Patricia	E. Battle
Raymond	Eugene Grant
Rudolph	Gasser
C	Marks
Susan	Healy
Tiffany	Dickson
Wanda	Wylam
Abigail	Rose Sheerer
Havana	Tidball
Phyllis	Claire D Dant
Beatriz	Cintron
Angelica	De la Fuente
Arona	Vashon
Betty	Webb

Colleen	Connors
Daniel	Bickel
Dawn	Black
Ruth	Waldram
Elizabeth	Juhnke
Elaine	Adams
Fritzie	M Wolfe
Heidi	Amdahl
Janice	C Wheat
Judy	Odell
Suellen	Johnston
Karen	Munz
Lorna	Griffith
Angela	Black
Mary	Kasprzyk
Robert	Walling
Pamela	Garand
Paul	McClintock
Patrick	Kirlin
Patrick	Russell
Rodney	Barker
Sarah	Bissell
Michael	and Kimberly Nolan
Rena	Morrill
Virginia	Amidon
Wendy	Sleisher
Jo	Connors
Bob	Carubia
Bridget	Robinson
Mary	Elizabeth
Donna	Trippett
Mary	S. Riley
Rebecca	Perez
Annette	Wiemann
Candy	Anderson
Earl	Pappenfuss
Glenn	Schueffner
Kaila	Haws
Irene	Robaidek
Cathy	Burt

Joan	Van Abel
Lily	Yu
Linda	Gabriel
Mallory	Keefe
Eva	Melenchuk
Michael	Rohde
Paul	Margan
Peter	Schaettle
Patrick	Haines
Philip	Helwig
Philip	L. Potratz
Pam	Kramer
Roger	Rohe
Roseann	Schmidt
Susan	DECKER
Timothy	Dutcher
John	Thomas Wells
Ann	Heller
Becky	Weber
Blake	Brodjeski
Denny	Christenson
Kim	Hakenjos
Karen	J. Murawski
Rebecca	Wensink
Betty	Holliday
Joseph	Michael Donnelly
Margaret	Erickson
Dana	Kinion
Michael	Peach
Judy	A. Cook
William	sturdevant
Nathan	Fitzpatrick
Zentura	Zentura
James	Willingham
Nahid	Amini
Eleni	Ruiz
Adrian	John Woollen
Kenneth	Abbott
Abby	Ettinger
Audrey	Coltrane

Abigail	McDuff
Abigail	LaFave
Anne	Blackburn
Amanda	Sorlie
Adsam	Robitaille
Adelle	Garner
Adria	Paya
Adrian	Vance
Aerik	La Fave
Aeryn	Elisabeth Anderson
Ariana	galicia
Genevieve	mary czech
Annette	Hirl
Aidan	Clarke
Aislynne	Van Oirschot
Anne	Kinskey
Amalia	Bauza
Alicia	Gonzalez
Allison	Cruz
Bobby	Jean
Allyson	Moseley
Althea	Sanny Vader
Amanda	Ficken
Marian	Lyon
Ashley	Grooms
Ann	Marie
Amyjo	Pleune
Andre	DZIERZYNSKI
Andrew	Davies
Aneka	Maurer
Angela	Jean Brown
Judy	Diciaccio
Angie	Griffin
Christina	Frazell
Anna	Romanchik
Melody	Pegis
Anna	Schumacher
Amy	Hoff
Arianna	Milbrand
Anna	Reese

Ann	Zacharias
Annie	McGregor Meek
Phyllis	Bassett
Alison	Gordon
Virgilio	A. Buhain
Aleena	Jenea Rivera
Angela	Rizzo
Armel	Valenzuela
Abigail	Hammitt
Ashley	Rahar
Ashley	Resto
Rachel	Mechling
Blake	Elsberry
Edie	Baars
Beverly	Lopp
Barbara	Beatty
Sarah	Jane
Roger	Bautista
Stroffe	Brandi
Rebecca	Jackson
Rebekah	Bull
Shana	Thomas
Bella	Silva
Betty	Morrison
Bianca	Saliba
Harry	Parker
Becky	Palmer
Blanche	Lefebvre
Joseph	Vasta
Bryan	M Nogaki
Mary	Lou Hesser
Barbara	Agresta
Bonnie	Knudsen
Bonnie	Norman
Emily	Gramley
Brandie	Campbell
William	Thomas Bray
Brettany	Schonert
Brittany	Boller
Anne	Brown

Bryan	Kelsen
Brynn	Turner
Phillip	Talarico
Maria	Buczek
Biviana	Carreon Valdez
Andrea	Cartwright
Kirk	Smith
Carol	A. Hood
Carleton	Black
Carmela	Cavero
Carmen	Parks
Carol	Baker
Roger	Joyal
Caryn	Spaniel
Cari	Asjes
Cassandra	Cobb
Catherine	Caroul
Catherine	Mary
Chris	Blount
Constance	M. Canute
Clarie	Denise Calicdan
William	Threlkeld
Callie	Grett
Stephanie	Kapp
Chandler	Barnato
Charles	Sproull
Carmel	Saliba
Chelsea	Meza
Chels	Rowe
Cherilyn	Cherilyn
Cheryl	L. Lambert
Lindsay	Beck
Chris	More
Cindy	Biery
Cindy	Aguirre
Vincenza	Agosta
Cynthia	Velky
Claire	Moore
Christina	Mesker
Elizabeth	Schantz

John	Robertson
Charity	Saweikis
Anbarasu	Jerald
Colleen	Kunsemuller
Dean	Schlueter
Chris	Cola
Charles	Otterpohl
Wayne	H. McNiel
Cristian	Alfaro
Charles	Sicola
Lisa	Holstein
Alison	Curtin
Cindi	Weeks
Cynthia	Peters
Stephen	Richardson
Dave	Miles
Jeanne	Kjellman
Dale	Nacke
Kathleene	Daly
Danae	Agnew
Danalyn	Alvarez Perez
Daniel	Ridder
David	Duppler
Davis	Posey
Deacon	Brian Zeman
Ken	Carpenter
Dorothy	Downing
Joan	Sessions
Dean	Clark
Deanna	Bridges
Debra	Ann Spence
Debrah	Kelley
Carmela	Deguara
Denise	Henderson
Carol	Denty
Devin	Andrews
Deb	Graber
David	Laub
David	Hofstra
Dave	Huizing

Diana	Ramirez
Dulce	Diaz
Sharon	Finecey
Denise	Rhodes
Daniel	Moore
Dominique	Muggeridge
Donald	Schatte
Donna	L. Graham
Ruth	Stoehr
Edward	J. Dowd
Jeanette	Owens
Gemma	Downey
John	Dulph
Bev	Martin
Jameela	Thomas
Cecilia	Keen
Andrew	Gillis
Denise	B. Slaven
David	Traut
Cliff	Schiewerden
Jerome	Matthews
Dustin	Slaton
Diane	Lebari
Dylan	Isaac Thaut
Emily	Simmons
Elizabeth	Knight
Elizabeth	A Nelson
Judah	Eaton
Evanan	Church
Erica	Chartier
Edgar	Manuel Chacón Lizano
Eva	A. Garay
Eric	Holsopple
Eileen	Ealy
Emily	Klein
Karen	Locker
Julie	Elander
Elizabeth	Bergeron
Elizabeth	Boriszek
Elizabeth	Abdool

Laura	Probst
Elizabeth	Earl May
Collyn	Hunt Gomez
Christy	Meyers
Erica	Marie Faucher
Emil	Ember
Emily	Medlyn
Emma	Leigh Hamilton
Emma	Hood
Emma	Jaquess
Enyer	Delgado
Elizabeth	Rankin
Erica	Mulford
Erica	Smith
Erik	Andersen
Erin	Myers
Ernest	Robillard
Esther	Attebery
Dee	Kelley
Faith	Zenaty
Fernando	Aizpun
Kolbe	Williams
Francis	Oberembt
Frances	Buchanan
$Frederick	Cohen
Aurora	Hampton
Mike	Fenton
Karla	Alvarado
Peter	Rappold
Christine	Gookin
Nancy	Bucca
Alicia	Thompson
Frank	B. Kady Jr.
Frances	Schmitz
Freda	Smouter
Gary	Henderson
Joseph	Martins
Tom	Sodano
Gabrielle	Vega
Elizabeth	Jean Hughes

Gabriela	Garcia
George	Berry
Gary	Anderson
Gregory	Antonik
Diana	Garcia
Gary	Raffle
Gaye	Drummond
George	Branscom
Gilbert	Cormier
Georgia	Farrish
Tim	Giles
Gillian	Owens
Gina	Schmittdiel
Mikell	Schoonover
Glenda	Patterson
Glen	Zimmerman
Grace	McAlary
Carolyn	S Gardner
Nancy	Baum
Kaitlyn	Schmitt
Kara	Schoepfer
Grace	Bergman
Gracelyn	Mosier
Annabelle	Gray
Katlynn	Green
Gregory	Smith
Gerald	Hicks
Patricia	Kumiega
Gabriel	Moreno
Deanne	Wikler
Catherine	Gwinner
Kerrie	Lynn Schlenker
Beau	Rodriguez
Hailee	Clifton
Hailey	Lennon
Carol	Theriault
Hannah	Kern
Hannah	Felch
Ida	Bolding
Caroline	Jordon

Gerard	Hartze
Harvey	B. Rachlin
Pamela	Faulkner
Nola	Kuester
Mary	Fairbairn
Heidi	Ngai
Anna	Roth
Ana	Paulson
Holly	Hanson
Hannah	Ferrin
Heather	Sargent
Paige	Hoban
Debra	Hoots
Hannah	Swartz
Lynne	Howell
Hannah	Janae Dean
Hoa	Vuong
Ian	Thompson
Tim	Kelley
Ronald	Draper
Nancy	M. Draper
David	Antoff
Isabel	Rothstein
Ashlie	Villafuerte
Isabella	Torres
Janine	Micke
Joyce	Carrico
Jacqueline	R. Krozy
Abigail	Allen
James	Fetty
Janaye	Pieczynski
Jane	Griffin
Janet	Cross
Janet	Waksmunski
Janice	Weber
Janie	Widman
Juan	Arguedas
Julia	Stamerro
Cynthia	Alfonso
Mae	Johnson

Jean	Vinyard
Gerard	Schmidt
Jeffrey	Aaron Borchardt II
Jeff	Frasieur
Jen	Brown
Jennifer	Larson
Jessica	Phillips
Jessica	Iwema
Jennifer	Hansley
James	Gokey
James	Harris
Jean	Hillberg
Linda	Stankiewicz
Joan	Null
Julianne	Wiley
Janet	Masline
Jim	Dobratz
John	Hammerbacher
Julia	Monk
Jean	Walkowski
Joy	M. Monroe
Juliana	Nordhoff
Joanna	Hobbs
Joann	Georgostathis
Joaquin	Gutierrez del Alamo
Joleen	Peterson
Joseph	Rebman
Michael	Brigadier
Joe	Wierzbicki
John	Gavin
John	E. Alexander
John	Kowalak
Dean	Allan Johnson
Patrick	Johnston
Jonathan	Dewey Wilkerson
Jordyn	Robinson
Josephine	Mortrud
Joseph	Bertin
Joyce	Simkin
Joyce	Hudgins

Starr	Powell
Patty	Straus
Jessica	Summers
Berl	Thompson
Sarah	Tomac
Hannah	Judson
Judith	Soller
Judy	Owensby Goad
Judy	Branscom
Julianna	Gallion
Charles	T and Julie R Arnold
Julio	Colmenares
Jennifer	Viviano
Jeremy	Day
Jolene	Wojcik
Jessica	Freeman
Ken	kruger jr
Kadynce	Owens
Blair	Kampoivtz
Kamy	Lee Treat
Kandace	maynard
Karina	Ortiz
Alia	Muellerleile
Katherine	Manning
Kate	Lessard
Kathleen	Gaber
Kathleen	RUTH GOLDSMITH-KILLING
Kathleen	M. Knospe
Katie	Palmatier
Katie	Gardner
Katie	Pace
Kayleen	Corrigan
Kathleen	B. Long
Kristen	Newcomer
Les	Greaser
Kathleen	Jenkins
Keaton	Dillard
Keili	Danielle Stevens
Kelly	Hellmuth

Kenna	Holt
Kristina	Kaufer
Kathryn	Haveman
Kim	Allmon
Nicole	Dodge
Kimberly	C. Martinez
Steve	King
Kira	O'Neal
Kirah	Fillmore
Kirk	Watts
Patricia	Doss
Katie	Bollinger
Kathy	Kelly
Kathrine	M Kolanko
Kristine	Schneider
Kay	West
Kevin	Nishimuta
Kenna	Thornton
Katherine	Ray
Kristina	Cobb
Karen	Salamon
Karen	Harris
Karen	Sipes
Katherene	Skinner
Kary	Taylor
Katherine	(Katie) Ramsey
Kenrith	Williams
Loisel	Barrios
Lacie	Barnes
London	Abigail Farnsley
Suzanne	Landis
Melanie	Hopkins
Launa	Meyer
Laura	Cheshire
Lauren	Parker
Lauren	Thurman
Diane	McGovern
Andrew	Leese
Katie	Lemon
Leonard	Reiland

Wilma	Lenz
Leslie	Holcomb
Linda	Gibbs
L.	GUNDIQUE
Luke	Brehm
Liana	Moore
Emily	Powell
Lily	Crosby
Lily	Sutton
Delaney	Tracy
Linda	BABB
Lindsey	Blount
Lindsey	Peter
Lisa	Johnson
Lisa	Burns
Lisabeth	Lipp
Lisa	Dahmer
Lisa	Hall
Olivia	Dean
Helen	Mary McBlain
Judith	Rangel
Larry	Garber
Lisa	COOLEY
Lois	A. Carter
Stephen	Gravel
Lorne	David Digges
Loretta	Nicholas
Louise	Cox
Louise	Perrotta
Megan	Luby
Luca	Castellanza
Lucy	Papaik
Luiz	Carlos
Lynda	Elliott
Lyndon	Griarte
Lynne	Perlik
Miss	Lynn Marie K
Mary	Brummell
Mark	Hagey
Martha	Ruschkamp

Samuel	Maclay
Madelyn	Peterson
Maryann	Derrick-Green
Madison	Selva
Maira	Tripp
Kristina	Gonzales
Sheree	Mann
Pinky	Mendoza
Maria	Kim
Jane	Klorer
Marian	Ross
Maria	P. Angelucci
Mariele	Lopez
H.R.	Martin
Marvin	Putman
Mary	T. Dombrovski
Mary	Hyska
Mary	Olson
Mary	Adams
Matalin	Shaver
Matt	Donald
Matthew	Snyder
Terrie	May
Mercedez	Barker
Marilyn	Stadtmueller
Moira	C. Dowling
Mckenna	Freeland
Maureen	Morton-Navarro
Marilyn	Lengyel
Mary	A. DURKIN
Kathleen	Mulhair
Monica	Ferris
Megan	Willis
Megan	Reinsfelder
Melinda	Movius
Melodie	Padgett
Michael	Morris
Mervyne	Greene
Gail	Dierkes
Mary	Cetera

Michael	Murray
Michael	Hinderscheid
Michael	van Holst
Michele	Cheever
Michelle	Lewis
Mikayla	Hill
Michalene	L. Lovato
Richard	Miles
Carlee	Miller
Mirna	Jajow
Michael	Gilbert
Jeanne	Ann White
Mary	Kay Neal
Michael	Dooley
Muriel	Korson
Margaret	Mary
Marilyn	Muscanere
Mary	Ann
Melvin	Molitor
Mary.	Leonard
Rosalynd	Perlick
Mona	Pilane
Maureen	Nash
Monica	Holland
Shannon	Moodry
William	Smith
Morgan	Matreci
Kary	Kahle
Matthew	Maurer
Lynda	True
Christina	Valadez
Julie	Kidwell
Mary	Lind
Michelle	Tripp
Olivia	Mullins
Mary	Venckus
Mark	Waters
Michael	Ingle
Mary	Partee
Bill	L. Manville

Natalie	Kurtz
Nadine	Schanilec
Nancy	Zaengle
Nancy	Yeats
Neida	Johnson
Augusto	Cesar
Nathan	Watry
Diana	Nelson
Mary	Ann
Nick	Unverferth
Nicole	Waters
Nicole	Dellas
Nicole	Maurer
Malielani	Min
Jacqueline	Aldrich
Nicole	Phipps
Mary	F. Norton
Natasha	Mosier
Noel	Perez
Noelle	Reagan
Jeff	Norton
Naomi	Murray
Michelle	Viljoen
Olivia	Cloer
Ciaran	O'Meara
Rocky	Rocha
Malorie	Summer
Órlaith	Ryden
Pamela	Hayward
Pamela	Burrell
Mary	R. Partin
Pauline	Self
Richard	Pauls
Phil	Stiver
Robert	Pierce
Martha	Maturi
Larry	Cotten
Keanna	Martin
Mary	Lou
Peggy	Kurtz

Robert	Collins
Portia	Horst
Emma	Brewer
Janet	Price
Pauline	Myers
Joseph	G. Sandoval
Pro-Life	Richardson
Rocky	Gray
Rebecca	Drinks
Ronnie	Rose
Robert	Chapman
Reagan	Marie Woody
Rebekah	Stepp
Crystal	Howley
Andrew	Reder
Regina	Calderon
Regina	Singleton
Renu	Carroll
Tyler	Revolinski
Robert	Reynolds
Ryan	Horning
Richard	Burkett
Rick	Hill
Kim	Hoog
Rosemary	Graham
Michael	Rosenthal-English
Royce	Clough
R.	Pescador
Renee	Show
Richard	Tuma
Sean	Hayes
Ruth	Merklinger
Ruthie	Johnson
Ruth	Nicolaus
Ryan	Leanor
Sharon	Larks
Sharon	Sackett
Sandra	Evarts
Olivia	David-Eagan
Bridget	Schlafley

Samantha	Cote
Charla	Moreno
Sara	Tracey
Sarah	Smith
Sarah	Brown
Sara	Yunger
Sara	Martin
Linda	Zimmerman
Scott	Bathke
Stephen	Brown
Alfred	Scott Jr.
Jeff	Weber
Sharon	Dakin
Sue	Gibson
Sarah	Tamburro
Dave	Pickrell
Susan	Gardy
Peter	Shaddock
Debbysue	Dettloff
Sharon	Ziegler
Mary	C. Shaw
Shellie	Silcott
Roberta	Sibbald
Larry	Simmons
Shelly	J. Taylor
Sydney	Keleske
Sharon	E. McCormick
Stacey	Manzi
Susan	Henebery
Kerri	Smith
Michael	Korn
Susan	Stepien
Sharon	Luke Sogut
Susan	Pingel
Jeanette	Rerucha
Stacey	R. Saia
Sally	Hess
Scott	Sprout
Patricia	Stack
Darlene	M. Champagne

Stasi	Ventura
Stasia	SCHWARTZ
Anastasia	Crain
Stephanie	Bennion
Stephaney	Roberson
Stephanie	Spandet
Stephanie	Veloso
Margaret	Stevenson
Eva	Stevy Young
Roy	Green
Jeff	Stoner
Sue	Jones
Sue	Shoemaker
Richard	Harrison
Susan M	Barker
Sukhdev	Contee
Ryleigh	Sullivan
Audrey	Summers
Susan	Hahn
Susan	M Walsh
Suzanne	Harmon
William	Sweeney
Allison	Howard
Sheila	Wisocky-Lord
Sylvia	Bertolini
Sylvia	bartosek gee
Sylvia	Galan
May	Tran
Maria	Tabellini
Lily	Ho
Tamra	Wright
Tarena	Mowrey
Taylor	Osowski
Tracy	Hernandez
Theresa	Bonopartis
Tiffany	Wilson
Antoinette	Disney
Tamara	Rutgers
Teresa	M Breault
Terri	L Monahan-Mitchell

Terry	Stam
Tressa	Hammond
Patricia	Munn
Theresa	Howard
Theresa	L. Greene
Timothy	Alberts
Timothy	Haunsperger
Christina	Haug
Valentina	Bernero
Jill	Campione
Delphene	Osborn
Thomas	Moran
Teresa	Robinson
R.	Thomas Conrad
Tony	Hamilton
Tonya	S Smith
Mike	Brown
Debra	Horton
Tim	Opper
Trace	Flax
Travis	bechtold
Terry	Hughes
Tresha	Rivere
Toby	Cobb
Thomas	X. Brown
Carol	Kemp
Melissa	Ducommun
Breanne	Wall
Virginia	Mantela
Valerie	Beukema
Valerie	Iacovangelo
Victoria	Whitmore
Vincent	Lagrotteria
Vickie	Giles
Veronica	Santini
Victoria	Leigh
Wendy	Pham
Cheryll	Klompien
William	Vandergriff
William	Baize

Amanda	Wildon
Wendy	Ridder
Kathleen	Worlund
Susang-Talamo	Family
Galen	W. Yoder
George	Akula
Yuerong	Hu
Abigail	Nolla
Zara	Elizabeth Dina
Claire	Sabroe
Linda	Webster
Zulmarie	Pagan-Panzardi
Robert	C Zunino
Zvonimir	Gašpar