Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. bio	re: Lieutenant Colonel Keith L. Roberts [partial] (1 page)	n.d.	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Ann O'Leary
OA/Box Number: 19575

FOLDER TITLE:
Fetal Protection Legislation [2]

2013-0436-S
rc1225

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Patti Fiscia
Brad
Candace
Jenny L
Sylvia M
Shelley P

7/22/99 conf. call

subcommittee markup - 7/30 (postponed)
dev Admin. views - policy analysis
Jeen asst as substitute
Not a role in subcommittee

Ofc of Tech Dev — working on issues
- views letters
- draft not for distribution to us.

INTERNAL Q&A ON ABORTION
July 21, 1999

Q: Air Force Lt. Colonel Keith Roberts is testifying today before the House Judiciary Subcommittee on the Constitution about a terrible incident of domestic violence, in which a pregnant woman was badly beaten by her husband, an Air Force serviceman, and miscarried as a result. The hearing will focus the Unborn Victims of Violence Act, sponsored by Representative Lindsay Graham, which would make it a separate federal offense to cause a pregnant women to miscarry or to cause other injury to the fetus during the commission of a pre-existing federal offense. What is the Administration's position on this legislation?

A: The Administration has not yet had a chance to review this legislation. Lt. Colonel Roberts is testifying only to the facts of a particular case, not representing our position. We intend to review the proposed legislation carefully.

SUBCOMMITTEE ON THE CONSTITUTION
Committee on the Judiciary
U.S. House of Representatives
Hearing on H.R. 2436, the "Unborn Victims of Violence Act of 1999"
Wednesday, July 21, 1999
1:30 p.m.; 2237 Rayburn House Office Building

WITNESS LIST

PANEL 1

Michael Lenz, Choctaw, OK

Lt. Colonel Keith Roberts, Deputy Chief, Military Justice Division, Air Force Legal Services Agency, Bolling Air Force Base, Washington, D.C.

Pamela B. Stuart, Attorney at Law

Ronald H. Weich, Partner, Zuckerman, Spaeder, Goldstein, Taylor & Kolker

The Honorable Terry M. Dempsey, Judge, District Court, 5th Judicial District, St. James, Minnesota

PANEL 2

Hadley Arkes, Edward Ney Professor of Jurisprudence and American Institutions, Amherst College

Juley Anna Fulcher, Public Policy Director, National Coalition Against Domestic Violence

Peter N. Rubin, Visiting Professor of Law, Georgetown University Law Center

Gerard V. Bradley, Professor, Notre Dame Law School

Statement of Michael Lenz
Before the Subcommittee on the Constitution
Hearing on H.R. 2436, the "Unborn Victims of Violence Act of 1999"
Wednesday, July 21, 1999

Committee members, I would like to give you some background on myself and my late wife Carrie Lenz.

We met in the spring of 1986. I had recently moved from the City of Tulsa to Oklahoma City. Carrie was a high school senior at Moore, OK. We began dating, she graduated high school and went on to College, and I took a job back in Tulsa and then in Ponca City. All the while, we maintained our relationship. I eventually took a job that required extensive travel around the country, and although it was difficult at times, our long distance relationship worked because we were both committed to the same ideas and goals. (Our plan) First, she would graduate from college. I would get promoted over the State of Oklahoma. Then we would get married, and when we thought we were mentally and financially prepared, we would have children.

While Carrie was attending college, she took a part time position with the Alcohol, Tobacco and Firearms under the "Stay in School" program. As the Oklahoma City ATF office grew, their need for a full time position grew as well. Carrie then transferred to a position with the U.S. Secret Service Administration under the same program until she graduated from college. After graduation, she accepted a position with the Drug Enforcement Administration through EBON, a company contracted with the Department of Justice to assist in the Asset Forfeiture

program. Since her first job with Federal Law Enforcement, Carrie and I were always extremely proud to be a part, albeit a small part, of our government.

Our plans all came together in the fall of 1991 (September 14) when we were finally married. Married...Yes. Financially ready to raise a family? Not Yet. That didn't come until 1993. Seven years after we first met, we believed we were finally ready to start our family.

I'm telling you all of this to give you some background on our relationship and our goals, and maybe to give you some insight on what it might be like to have a seven-year plan blown up in your face.

We began trying to have children 1993. After several months with no success, we sought assistance from a fertility doctor who put Carrie on some medication, and we continued our efforts at beginning a family. With no success, in early 1994 the doctor recommended exploratory surgery, which she under went. A few months later, she informed me that she was pregnant. We were so thrilled, but our excitement would not last long. With weekly monitoring, the doctor discovered Carrie had an ectopic pregnancy and that the fetus had died. In November of that same year, Carrie again informed me that she was pregnant, and we both prayed that this would prove a better pregnancy than the first. The doctor confirmed our hopes by telling us everything appeared to be healthy and normal at our first ultrasound.

In the months that followed, we prepared our home for the new baby. We purchased a

changing table and baby bed, and Carrie was trying to get the nursery ready when we decided it would be easier if we knew the sex of our child. We didn't have a set name if the child was a girl, but if we were having a boy, we had both agreed his name would be Michael James Lenz, III. So on the afternoon of April 18, 1995, we met at the hospital for an additional ultrasound to determine the sex of our baby. Carrie was so nervous. As I held her hand, the pictures on the monitor came into view. The heart beat, a little hand and arm, and then you could see the face of our child. Finally the baby moved a little, and the nurse said "Congratulations! You're having a boy!" We looked at each other and said simultaneously, "Michael James Lenz, III." He had his name. Then, with a kiss and "I Love You," I left the room. We were so happy we even paid for extra ultrasound pictures to show off. When we arrived home that evening, we called all of our friends and relatives to tell them the news. We didn't know it at the time, but that would be the last time Carrie spoke to the people she loved most.

The next the morning Carrie, who was usually 15 to 20 minutes late to work, left the house early to show everyone at work the pictures of our son, Michael. I left for work at about 8:30 that morning, a happy, expectant father of my first child . . . my son . . . Michael. At 9:02 A.M. on April 19, 1995, it all shattered, when the Alfred P. Murrah Federal Building was blown up. A seven-year plan, gone. Just Blown up. At 9:03 A.M. that morning I was no longer an expecting father or husband. At 28 years old, I was a widower.

I don't care to go into the details of what happened to me in the months followings the bombing, but please ask yourself, "Would having a part of your loved one in the form of a child

ying to get the nursery ready when we decided it
l. We didn't have a set name if the child was a
agreed his name would be Michael James Lenz,
met at the hospital for an additional ultrasound to
ervous. As I held her hand, the pictures on the
e hand and arm, and then you could see the face of
the nurse said "Congratulations! You're having a
aneously, "Michael James Lenz, III." He had his
ft the room. We were so happy we even paid for
e arrived home that evening, we called all of our
didn't know it at the time, but that would be the
nost.

usually 15 to 20 minutes late to work, left the
res of our son, Michael. I left for work at about
my first child . . . my son . . . Michael. At 9:02
the Alfred P. Murrah Federal Building was blown
At 9:03 A.M. that morning I was no longer an
I was a widower.

at happened to me in the months followings the
ng a part of your loved one in the form of a child

would make your grieving easier?" I think it would. Therefore, the loss of that potential life is worth an immeasurable amount to me. Let's say for the sake of argument that Carrie was not killed by that act of violence, but that shrapnel entered the womb and killed Michael. Is it safe to assume that would have an ill effect on her child bearing capacity, not only physically, but emotionally, for the rest of her life? I am no doctor, but I would have to think it would. In this scenario, a seven-year plan is still gone and possibly any future plans. Should we as people allow that act of violence to remain a victimless crime? No Michael the 3rd ever mentioned? I don't think that would be right. In any case, I lost the two people I loved most that day, and the official death toll for the Murrah Bombing remains at 168. In addition to Carrie, there were two other expecting mothers in the building that day that died. Three babies.

Passing this bill won't bring my wife and son back to me, but it would go along way toward at least recognizing Michael's life and the loss of seven years of responsible actions to gain that life. Violent criminal acts that result in the death of a potential life is worth prosecution on its own merits, regardless of the other counts against the defendant. As the only survivor of a family of three, in my case, it would only be right. Regardless of your vote on this, in my mind 171 people lost their lives that day, and three "Daddies to be" became widowers.

Thank You for your time. Michael James Lenz, Jr

Statement of Michael Lenz
Before the Subcommittee on the Constitution
Hearing on H.R. 2436, the "Unborn Victims of Violence Act of 1999"
Wednesday, July 21, 1999

Committee members, I would like to give you some background on myself and my late wife Carrie Lenz.

We met in the spring of 1986. I had recently moved from the City of Tulsa to Oklahoma City. Carrie was a high school senior at Moore, OK. We began dating, she graduated high school and went on to College, and I took a job back in Tulsa and then in Ponca City. All the while, we maintained our relationship. I eventually took a job that required extensive travel around the country, and although it was difficult at times, our long distance relationship worked because we were both committed to the same ideas and goals. (Our plan) First, she would graduate from college. I would get promoted over the State of Oklahoma. Then we would get married, and when we thought we were mentally and financially prepared, we would have children.

While Carrie was attending college, she took a part time position with the Alcohol, Tobacco and Firearms under the "Stay in School" program. As the Oklahoma City ATF office grew, their need for a full time position grew as well. Carrie then transferred to a position with the U.S. Secret Service Administration under the same program until she graduated from college. After graduation, she accepted a position with the Drug Enforcement Administration through EBON, a company contracted with the Department of Justice to assist in the Asset Forfeiture

program. Since her first job with Federal Law Enforcement, Carrie and I were always extremely proud to be a part, albeit a small part, of our government.

Our plans all came together in the fall of 1991 (September 14) when we were finally married. Married...Yes. Financially ready to raise a family? Not Yet. That didn't come until 1993. Seven years after we first met, we believed we were finally ready to start our family.

I'm telling you all of this to give you some background on our relationship and our goals, and maybe to give you some insight on what it might be like to have a seven-year plan blown up in your face.

We began trying to have children 1993. After several months with no success, we sought assistance from a fertility doctor who put Carrie on some medication, and we continued our efforts at beginning a family. With no success, in early 1994 the doctor recommended exploratory surgery, which she under went. A few months later, she informed me that she was pregnant. We were so thrilled, but our excitement would not last long. With weekly monitoring, the doctor discovered Carrie had an ectopic pregnancy and that the fetus had died. In November of that same year, Carrie again informed me that she was pregnant, and we both prayed that this would prove a better pregnancy than the first. The doctor confirmed our hopes by telling us everything appeared to be healthy and normal at our first ultrasound.

In the months that followed, we prepared our home for the new baby. We purchased a

changing table and baby bed, and Carrie was trying to get the nursery ready when we decided it would be easier if we knew the sex of our child. We didn't have a set name if the child was a girl, but if we were having a boy, we had both agreed his name would be Michael James Lenz, III. So on the afternoon of April 18, 1995, we met at the hospital for an additional ultrasound to determine the sex of our baby. Carrie was so nervous. As I held her hand, the pictures on the monitor came into view. The heart beat, a little hand and arm, and then you could see the face of our child. Finally the baby moved a little, and the nurse said "Congratulations! You're having a boy!" We looked at each other and said simultaneously, "Michael James Lenz, III." He had his name. Then, with a kiss and "I Love You," I left the room. We were so happy we even paid for extra ultrasound pictures to show off. When we arrived home that evening, we called all of our friends and relatives to tell them the news. We didn't know it at the time, but that would be the last time Carrie spoke to the people she loved most.

The next the morning Carrie, who was usually 15 to 20 minutes late to work, left the house early to show everyone at work the pictures of our son, Michael. I left for work at about 8:30 that morning, a happy, expectant father of my first child . . . my son . . . Michael. At 9:02 A.M. on April 19, 1995, it all shattered, when the Alfred P. Murrah Federal Building was blown up. A seven-year plan, gone. Just Blown up. At 9:03 A.M. that morning I was no longer an expecting father or husband. At 28 years old, I was a widower.

I don't care to go into the details of what happened to me in the months followings the bombing, but please ask yourself, "Would having a part of your loved one in the form of a child

ying to get the nursery ready when we decided it
l. We didn't have a set name if the child was a
agreed his name would be Michael James Lenz,
met at the hospital for an additional ultrasound to
ervous. As I held her hand, the pictures on the
e hand and arm, and then you could see the face of
the nurse said "Congratulations! You're having a
aneously, "Michael James Lenz, III." He had his
ft the room. We were so happy we even paid for
e arrived home that evening, we called all of our
didn't know it at the time, but that would be the
nost.

usually 15 to 20 minutes late to work, left the
res of our son, Michael. I left for work at about
my first child . . . my son . . . Michael. At 9:02
the Alfred P. Murrah Federal Building was blown
At 9:03 A.M. that morning I was no longer an
I was a widower.

at happened to me in the months followings the
ing a part of your loved one in the form of a child

would make your grieving easier?" I think it would. Therefore, the loss of that potential life is worth an immeasurable amount to me. Let's say for the sake of argument that Carrie was not killed by that act of violence, but that shrapnel entered the womb and killed Michael. Is it safe to assume that would have an ill effect on her child bearing capacity, not only physically, but emotionally, for the rest of her life? I am no doctor, but I would have to think it would. In this scenario, a seven-year plan is still gone and possibly any future plans. Should we as people allow that act of violence to remain a victimless crime? No Michael the 3rd ever mentioned? I don't think that would be right. In any case, I lost the two people I loved most that day, and the official death toll for the Murrah Bombing remains at 168. In addition to Carrie, there were two other expecting mothers in the building that day that died. Three babies.

Passing this bill won't bring my wife and son back to me, but it would go along way toward at least recognizing Michael's life and the loss of seven years of responsible actions to gain that life. Violent criminal acts that result in the death of a potential life is worth prosecution on its own merits, regardless of the other counts against the defendant. As the only survivor of a family of three, in my case, it would only be right. Regardless of your vote on this, in my mind 171 people lost their lives that day, and three "Daddies to be" became widowers.

Thank You for your time. Michael James Lenz, Jr

July 21, 1999

TESTIMONY OF

PAMELA B. STUART, ATTORNEY & COUNSELLOR AT LAW
FORMER FEDERAL PROSECUTOR

concerning H.R. 2436
The Unborn Victims of Violence Act of 1999

Pamela B. Stuart
Attorney & Counsellor at Law
888 Sixteenth St., NW
Washington, DC 20006
202-835-2200
202-835-2202 (fax)

I. Introduction

Good Afternoon. I am Pamela Bruce Stuart. I am an attorney in private law practice but I am here today to speak from the perspective of a former federal prosecutor. I am a member of the bar in New York, the District of Columbia, Florida, Maryland and Virginia. I appreciate the opportunity to assist the Constitution Subcommittee as it considers H.R. 2436, the Unborn Victims of Violence Act of 1999.

I have been asked to appear this afternoon because I served as

an Assistant United States Attorney and later as a trial attorney in the Office of International Affairs of the Criminal Division of the United States Department of Justice for eight and a half years. Since the object of this bill would be to amend the federal criminal laws to add a new separate offense for criminal acts that cause the death of or bodily injury to fetuses, I hope to be able to impart the "real world" perspective of a working prosecutor who might be called upon to indict a case under this proposed law and try to win a conviction before a jury.

We in the current and former prosecutor community are well aware of the problem of violence, particularly domestic violence, that is perpetrated against women. Most of these criminal acts do not involve interstate activity or other concerns that typically invoke the interest of federal authorities, other than the use of a firearm. The criminal activities that would be addressed by this bill are already the subject of either state or federal criminal laws, or both, so that no additional criminals would be prosecuted as a result of the enactment of this legislation. By definition, if you kill or assault the mother of a fetus, you have committed a criminal act that is punishable under state and/or federal law. So, the question then is what, if anything, would this legislation add to the enforcement scheme that presently exists and what damage, if any, might it do to the ability of prosecutors to secure convictions on the underlying charges against the person charged?

I am very sympathetic to the goal of trying to curb violence against women through the use of the criminal laws, but I fear that this bill as currently drafted will hurt the ability of federal prosecutors to secure convictions against those who perpetrate

violence against women who happen to be pregnant at the time that they become victims of crime. Obviously, such an outcome would be exactly the opposite of the intended result.

II. Personal Background

I think it would be helpful in assessing my comments for you to know something about my background. I graduated from Mount Holyoke College in 1970 and the University of Michigan Law School in 1973. I arrived in Washington during the summer of the Watergate hearings and then spent 5-1/2 years prosecuting consumer fraud cases at the Federal Trade Commission. From 1979 to 1985, I served as an Assistant United States Attorney for the District of Columbia. I appeared daily in the local and federal courts of the Nation's Capital. I prosecuted everything from misdemeanor thefts up through complex federal fraud cases. I tried approximately 50 jury trials and, with the concurrence of grand juries, obtained indictments in hundreds of felony cases. I argued appeals of criminal cases before the District of Columbia Court of Appeals and the US Court of Appeals for the District of Columbia Circuit. In 1985, I joined the Office of International Affairs of the Criminal Division of the US Department of Justice where I assisted prosecutors all over the United States and abroad in prosecuting cases that required international extradition or sharing of evidence. In 1987, I entered private practice and have been primarily a civil and white collar criminal defense attorney ever since. I have represented some clients in Congressional investigations. For example, I helped represent Senator Packwood before the Senate Ethics Committee.

In all of my years as a prosecutor, I do not recall handling a case in which the victim of the crime was pregnant at the time of the commission of the offense. I may have done so, but I do not recall any such cases. From my personal experience, I would extrapolate that such cases are rare.

Yesterday, when I learned that I was to testify on this topic, I searched for any relevant cases in Lexis. I discovered that this issue arises primarily in the context of vehicular homicide cases in which the victim of a fatal car collision is pregnant. This was of interest to me as I tried a precedent-setting case of murder while armed with a car here in the District of Columbia.

In that connection, I should note that while I served last year as the president of the Assistant United States Attorneys Association of the District of Columbia, an organization of current and former federal prosecutors, and am currently a member of the Board of Directors of the Bar Association of the District of Columbia, the views I express here today are entirely my own. I do not represent any organization or special interest.

III. The Unborn Victims of Violence Act of 1999

I would like to turn now to the proposed legislation that I have been asked to review. H.R. 2436 would amend various sections of Title 18 of the United States Code and the Uniform Code of Military Justice to make it a separate offense to engage in conduct violating the statute which thereby causes the death of or bodily injury to "a child, who is in utero at the time the conduct takes place." It would prohibit the prosecution of any person for conduct relating to a consensual abortion, for medical

treatment, and would prohibit prosecution of conduct by the mother with respect to her unborn child.

As I indicated, by definition, this legislation would not apprehend one additional criminal because, in order to be guilty of an offense under this proposed bill, one would already have to have committed an act that violates Title 18. What appears to be the intent of the drafters of the bill is to enhance the punishment that would be given to one who, in the commission of another criminal act, causes the death or injury of a fetus.

In thinking about this possibility, I am mindful of the concern that has been raised often in the current and former prosecutor community as well as among criminal defense attorneys that the Congress is "federalizing" the criminal law. By that I mean that the Congress has legislated into the federal criminal code many criminal offenses that normally would be covered by state criminal laws. The problem with this trend is that it has a tendency to overburden the federal courts with cases that could be efficiently and effectively handled by the state courts. By adding federal offenses that might otherwise be legislated by the states, the judges and prosecutors, probation officers, US Marshals, courtroom clerks and others who work in the federal courts must take time away from other criminal cases in which the federal interest is more apparent -- such as interstate kidnapping or cases against organized crime -- to handle what are essentially domestic violence cases or cases involving violent crimes that have traditionally been the province of state courts. The result of this trend has been, among other things, to delay civil cases as well as other criminal cases. Because of

the federal Speedy Trial Act, criminal cases take priority on the calendar of every federal judge. To the extent that they are getting cases that could otherwise be handled in state courts, this is a waste of precious federal resources and delays justice for other litigants.

In the case of this particular bill, we are not dealing with a positive enhancement of the ability of federal prosecutors to fight crime such as the money laundering statutes or those that target organized crime. Rather, this bill would merely create a second offense for punishment purposes. More importantly, from my point of view, the bill might have the unintended consequence of making it more difficult to convict the very perpetrators that the members of the Subcommittee wishes to punish more severely!

IV. The Practical Implications of the Bill -- will prosecutors be assisted or thwarted in their efforts to convict criminal wrongdoers

While it is definitely the prerogative of the Congress to enact legislation, ultimately the prosecution of the proposed criminal statute will be left to the Assistant United States Attorneys all across the country. Will this bill help them or hamstring them? My concern is that the proposed bill would be a prosecutor's nightmare. I am concerned that this proposed statute is open to attack on several fronts.

A. Proof problems

As worded, a prosecutor trying to persuade a grand jury to indict a case under this statute would have to allege and prove by a preponderance of the evidence to the satisfaction of a majority of the 23 member grand jury and later beyond a reasonable

doubt at trial that:

(1) the defendant engaged in conduct that violated the specified sections of Title 18 that was directed at a woman who was pregnant at the time of the offense;

(2) that the criminal conduct (whatever it was) caused the death of or bodily injury to the fetus beyond a reasonable doubt;

(3) that the defendant had a culpable mental state (he knowingly and intentionally caused the death or bodily injury to the fetus)

(4) that the defendant was not at the time of the offense engaged in conduct relating to an abortion for which the pregnant woman had given or impliedly given consent;

(5) that the defendant was not at the time of the offense engaged in providing any medical treatment to the woman or her unborn child; and

(6) that the defendant was not engaged in conduct directed at her own unborn child at the time of the offense.

Unlike the civil justice system, the criminal law demands a culpable state of mind (mens rea) as well as an act in violation of the law. There is no strict liability in crime. One cannot be put in jail for committing a crime unless he or she intended that the crime occur -- or at least acted knowingly and willfully. Thus, it would be possible that a perfectly good criminal case against a defendant who, for example, assaulted a woman on a federal reservation, and was charged with the offense of also injuring her unborn fetus, would degenerate into a heated debate among jurors as to whether

the perpetrator knew the victim was pregnant and intended to harm the fetus.[1]

Beyond a debate over the defendant's knowledge or lack thereof of the victim's condition (pregnancy), the requirement of proving that the criminal conduct caused the death or bodily injury of the fetus beyond a reasonable doubt would be an evidentiary nightmare. First, the prosecutor would have to prove that the fetus was alive and well prior to the criminal conduct. That would require expert testimony, probably from the mother's gynecologist or an emergency room physician. Unlike forensic pathologists who often work for the government, physicians in private practice are difficult to schedule for testimony. If, as may be the case with assaultive conduct in a remote location, the victim is not found and treated within a few minutes after the event, a perfectly good prosecution for assaultive conduct against the woman would be sidetracked into a raging debate as to whether the assault caused the death of the fetus or whether the child was stillborn.[2]

Secondly, the prosecutor would have to show, to the exclusion of all other reasonable causes, that the criminal conduct was the proximate cause of the death or bodily injury to the fetus. With all of the other things that can go wrong in utero (placental abruption, hypoxia, etc. -- to name just a few) and in the birth process, it may be difficult to establish, beyond a reasonable doubt, that the criminal conduct

---

[1] There is a possible "transferred intent" that would assist in these circumstances.

[2] I have represented a number of plaintiffs in brain-damaged baby cases stemming from medical malpractice at birth and it is astonishing the number of theories defense experts can come up with to explain the death of a newborn due to pre-natal injuries rather than the negligence of health professionals.

caused the injury. Needlessly complex medical testimony would be required and jurors might become overwhelmed and confused.

Moreover I can easily imagine that if the case ever got to the jury room that well-intentioned jurors might endlessly debate the issue of whether the fetus was an "unborn child" -- that is, whether the fetus had reached the stage where it was viable.

Because of the raging national debate on what legal rights a fetus has, a jury might be sidetracked into a debate as to what is an unborn child and whether it has to be viable and whether a child created in a petri dish would count. Such a possibility would, to say the least, detract from the ability of a prosecutor to try a clean case and achieve a conviction. It would also result in needlessly protracting jury deliberations which would use up court time.

I can also foresee endless opportunities for defense attorneys to challenge the constitutionality of the statute and thus delay the swift and sure conviction that is the desired end of the prosecutor. All of this would merely detract from what, by definition, was already a viable criminal prosecution under existing federal law.

So, in my opinion, this bill would not add anything to existing law and would detract from the ability of federal prosecutors to fight crime.

V. Other, More Viable, Options

Since the major objective of this bill is to enhance the punishment of persons who commit crimes against pregnant women, the Subcommittee might wish to focus on amending the criminal laws with respect to punishment in order to permit the

enhancement of a sentence based upon injury to the fetus carried by a pregnant victim of crime. An amendment to 18 U.S.C. § 3558(d) which provides for death or imprisonment for certain crimes against children to provide courts with the authority to impose additional punishment for the death or injury of fetuses resulting from crimes against their mothers might be appropriate. I would suggest that it would be easier for a prosecutor to prove causation in the context of sentencing rather than having to prove it to the satisfaction of a jury beyond a reasonable doubt. By putting the issue in the sentencing phase of a case, it would also remove the possibility that civil liability of others involved in the death or injury of the fetus might be precluded by a finding beyond a reasonable doubt that a particular criminal caused the death.

In addition, Congress might wish to make known to the U.S. Sentencing Commission, which has already provided for enhancement of punishment ("adjustment" in their vernacular) for a vulnerable victim that Congress specifically wishes pregnant women included within the category of "vulnerable" victims. The federal sentencing guidelines in § 3A1.1 provide that if the finder of fact at trial or, in the case of a plea, the court finds at sentencing beyond a reasonable doubt that the defendant selected his victim as the object of the offense because of gender (actual or perceived), the sentencing calculation may be increased by 3 levels. If the court or jury finds that the defendant knew or should have known the victim of the offense was a vulnerable victim, the calculation is to increase by two levels. This enhancement is not applied in the case of a sexual offense because that factor is taken account in determining the base offense level of the applicable guideline. The current

definition of a vulnerable victim is (a) a person who is a victim of the offense of conviction and any conduct for which the defendant is accountable under § 1B1.3 (relevant conduct) and (b) who is unusually vulnerable due to age, physical or mental condition, or who is otherwise particularly susceptible to the criminal conduct.

Also, as a result of the Victim Witness Protection Act of 1982, prosecutors and probation officers solicit statements by or on behalf of victims of crime detailing their financial and emotional losses for consideration at sentencing. In this way, the loss of a pregnant woman's fetus may be brought to the attention of the sentencing court.

IV. Legal History

Not only are there available means for Congress to accomplish the goals of this legislation short of injuring the ability of prosecutors to obtain convictions, but the Congress should bear in mind that the weight of legal authority in history would not support a finding that an unborn child can be a separate victim of a criminal offense. The common law, as far back as 1648, held that an unborn fetus, viable or otherwise, could not be the subject of homicide. State of Connecticut v. Anonymous, 40 Conn. Supp. 498, 516 A.2d 156 (Super. Ct. CT. 1986), citing 3 Coke, Institutes (1648)("If a woman be quick with childe, and by a potion or otherwise killeth it in her wombe, or if a man beat her, whereby the childe dyeth in her body, and she is delivered of a dead childe, this is a great misprison [i.e., misdemeanor], and no murder; but if the childe be born alive and dyeth of the potion, battery, or other cause, this is murder; for in law it is accounted a reasonable creature, in rerum natura, when it is born alive"). In the 18th century, Coke's requirement that the infant be born alive in order to be the

subject of a homicide was reiterated and expanded by both Blackstone in his Commentaries (1765) and Hale, Pleas of the Crown (1778), p. 433; see also, 1 Hawkins, Pleas of the Crown (1762), ch. 31 @ 16. In the mid 19th century, a series of prosecutions in the English courts against women accused of murdering a newborn were brought in which the court instructed that a child had to be "actually wholly in the world in the living state to be the subject of a charge of murder." See Keeler v. Superior Court of Amador County, 2 Cal.3d 619, 470 P.2d 617, 87 Cal. Rptr. 481 (1970).

By 1850, this rule had been long accepted in the United States. As early as 1797, proof that the child was born alive was ruled to be necessary to support an indictment for murder. However, some state legislatures enacted feticide statutes beginning with New York in 1829 which said that the wilful killing of an "unborn quick child" by any injury to the mother of such child, which would be murder if it resulted in the death of the mother, would be deemed manslaughter in the first decree. Five other states (Missouri, Arkansas, Michigan, Mississippi, and Wisconsin) enacted statutes declaring feticide to be a crime punishable as manslaughter. The New York Court of Appeal in Evans v. People, 49 N.Y. 86 (1872) restricted the statute to its terms and said that death cannot be caused when there is no life. Almost every state court that has had a homicide statute that did not define "human being" as explicitly including a fetus have held that the words "person" or "human being" would not include the unborn child or fetus. In two state court decisions, the courts recognized that the pre-existing common law did not recognize the killing of an unborn child as

"homicide" but felt they had the authority to change the law prospectively to recognize modern medical technology. See Commonwealth v. Cass, 392 Mass. 799, 467 N.E.2d 1324 (1984); State v. Horne, 282 S.C. 444, 319 S.E.2d 703 (1984). Some states have imposed criminal liability by statute for causing the death of a fetus.

In Roe v. Wade, 410 U.S. 113, 35 L.Ed.2d 147, 93 S.Ct. 705 (1973), the Supreme Court held that a nonviable fetus was not a "person" for purposes of the Fourteenth Amendment. The overwhelming majority view in the United States is that a nonviable fetus has no right to bring an action for wrongful death. Miccolis v. AMICA Mutual Insurance Co., 587 A.2d 67, 71 (R.I. 1991). It has no property rights until it is born alive.

Conclusion

For reasons both practical and legal, the Congress should not enact H.R. 2436. It would have the unintended consequence of taking a clean and neat prosecution of a criminal act and turning it into an opportunity for defense attorneys to inject the national debate over what legal status an unborn child should have into the deliberations of lay jurors with disastrous consequences for a federal prosecutor. Otherwise guilty defendants might go free as a result. I ask you not to favorably report out this bill in its present form.

STATEMENT OF

LIEUTENANT COLONEL KEITH L. ROBERTS

UNITED STATES AIR FORCE

BEFORE THE

SUBCOMMITTEE ON THE CONSTITUTION

COMMITTEE ON THE JUDICIARY

HOUSE OF REPRESENTATIVES

ON THE "UNBORN VICTIMS OF VIOLENCE ACT OF 1999"

21 JULY 1999

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. bio	re: Lieutenant Colonel Keith L. Roberts [partial] (1 page)	n.d.	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Ann O'Leary
OA/Box Number: 19575

FOLDER TITLE:
Fetal Protection Legislation [2]

2013-0436-S
rc1225

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Biography

UNITED STATES AIR FORCE

Air Force Legal Services Agency, Bolling AFB, DC 20332

LIEUTENANT COLONEL KEITH L. ROBERTS

Lieutenant Colonel Keith L. Roberts is Deputy Chief, Military Justice Division, Air Force Legal Services Agency, Bolling Air Force Base, Washington D.C. Colonel Roberts was born in (b)(6) and graduated from (b)(6) with honors. He then attended [0017] Washburn University, Topeka, Kansas, and graduated *cum laude* with a BA in Sociology-Anthropology. He attended Washburn University School of Law and received a Juris Doctor degree. Colonel Roberts received his Air Force commission through the Air Force Reserve Officer Training Corps program at Washburn University and in May 1981 was assigned to the Office of the Staff Judge Advocate, 347th Combat Support Group, Moody Air Force Base, Georgia. In May 1983 he was reassigned to the Office of the Staff Judge Advocate, 86th Tactical Fighter Wing, Ramstein Air Base, Germany. From June 1986 to August 1989, Colonel Roberts served as the Staff Judge Advocate, Headquarters, Air Force Reserve Officer Training Corps, Maxwell Air Force Base, Alabama. He then attended the Air Force Air Command and Staff College, Maxwell Air Force Base, Alabama, from August 1989 to June 1990. In June 1990 Colonel Roberts became the Staff Judge Advocate, 384th Bombardment Wing (H), McConnell Air Force Base, Kansas. From July 1993 to August 1996 he served as Deputy Chief, Military Justice Division, Air Force Legal Services Agency, Bolling Air Force Base, Washington, D.C. During that assignment he also served as Staff Judge Advocate, Joint Task Force 160, Guantanamo Bay, Cuba, from February to July 1995. Colonel Roberts served as a Military Judge, assigned to the Air Force Legal Services Agency, Eastern Judicial Circuit, Bolling Air Force Base, from August 1996 to August 1998. He assumed his current position in August 1998.

Colonel Roberts is admitted to practice law before the Kansas Supreme Court, the U.S. Federal District Court for the District of Kansas, and the U.S. Court of Appeals for the Armed Forces.

Awards and decorations include the Defense Meritorious Service Medal, the Meritorious Service Medal with four Oak Leaf Clusters, the Air Force Commendation Medal, the Air Force Achievement Medal, the Joint Meritorious Unit Award, the Air Force Outstanding Unit Award with one Oak Leaf cluster, the Air Force Organizational Excellence Award with two Oak Leaf Clusters, the National Defense Service Medal, and the Humanitarian Service Medal. He was the Air Training Command Outstanding Judge Advocate for 1988.

Colonel Roberts is married to the former Jennifer O'Brate of (b)(6) They have two sons, Jason and Michael.

My name is Lieutenant Colonel Keith Roberts and I am an active duty Air Force Judge Advocate currently serving as the Acting Chief of the Air Force Military Justice Division of the United States Air Force Judiciary at Bolling Air Force Base, Washington, D.C. The Military Justice Division is responsible for all military justice policy matters in the Air Force. I have been the Deputy Chief of the Division approximately four years, and my previous assignments included duty as a military judge, three assignments as a Staff Judge Advocate and two other base-level assignments.

I am appearing today at the request of the Subcommittee for the purpose of presenting the facts in the court-martial case of *United States v. Airman Gregory A. Robbins*, and the application of the Assimilative Crimes Act to that case. Neither my testimony or appearance here today should be construed as an endorsement of H.R. 2436 by me, the Air Force, the Department of Defense or the Executive Branch. It is my understanding that neither DoD nor the Executive Branch have completed their review of this legislation.

While I had no personal involvement in this case, in preparation for these hearings I reviewed the court-martial record of Airman Gregory A. Robbins. My statement includes a brief summary of the case that I took primarily from a Stipulation of Fact signed by Airman Robbins and his guilty plea discussion with the military judge conducted under oath at his trial. My

statement also includes a discussion of one particular charge that assimilated an Ohio statute.

STATEMENT OF FACTS

Airman Robbins and his wife, Karlene, were married on 28 December 1995. In February 1996, Airman Robbins arrived at Wright-Patterson Air Force Base, Ohio, his first permanent duty assignment, and the couple began living together as husband and wife. The same month, Mrs. Robbins became pregnant. In mid-March 1996, they moved into military base housing located at 137 Trunk Drive, an area of exclusive federal jurisdiction on Wright-Patterson Air Force Base, Ohio. Mrs. Robbins' anticipated delivery date was 26 October 1996.

Shortly after the couple moved into base housing, Airman Robbins began beating his wife. The abuse always occurred within the confines of the house. It began with pushing, then escalated to open-handed hitting, then punching, and finally kicking. During these episodes, Airman Robbins struck Mrs. Robbins on various parts of her body, including her legs, her side, her back, her head, and her face. Sometimes, he hit her with enough force to drop her to her knees.

A variety of factors reportedly motivated Airman Robbins' assaults. At times, he was angry with his wife for not cleaning the house or not letting the couple's two dogs out. At other times, he was angry about her care of

their pet birds. Sometimes he was angry about his wife's long-distance phone calls to her mother in Chicago and the expenses incurred from them. There is no evidence that Mrs. Robbins brought any of these instances of physical abuse to the attention of military authorities, prior to the September incident.

After the episodes described above, Mrs. Robbins periodically packed her bags with the thought of leaving her husband and returning to Chicago. However, she always changed her mind and stayed.

On 12 September 1996, Mrs. Robbins was approximately 34 weeks pregnant. The fetus had no known abnormalities. Airman Robbins came home that evening, noticed one of the dogs had defecated on the floor near the bathroom door, and became enraged. Airman Robbins then began yelling at his wife as she tried to defend the dog. Next, he pushed her, causing her to fall to her knees. When she tried to escape, he pursued her down the stairs, and cornered her against a wall. He then wrapped his fist in a uniform tee shirt and began repeatedly punching Mrs. Robbins in the face with a closed fist, breaking her nose and battering her eye. He then began punching her in the abdomen, while she attempted to shield herself with one hand on her back and the other on her stomach. The blows to Mrs. Robbins' abdomen were so severe that they ruptured her uterus and caused the placenta to separate from the uterus. Mrs. Robbins was

eventually able to escape to a neighbor's house. The neighbors immediately called for an ambulance and Mrs. Robbins was taken to the base medical center.

On her arrival, Mrs. Robbins' face was swollen and bruised, her right eye was swollen shut, and she was losing blood internally in the abdominal area. An ultrasound detected no amniotic fluid and no fetal heart tones. The doctors determined that immediate surgery was needed. Mrs. Robbins had lost two liters of blood from the rupture, and the placenta was entirely torn from her uterine wall. Doctors estimated that, had she not reported the assault, Mrs. Robbins would have died of blood loss within hours. After eight days of inpatient care, Mrs. Robbins was flown by medical aero-evacuation to her home in Chicago for further recovery. A forensic pathologist performed an autopsy on the fetus and the local Deputy Coroner opined that the cause of fetal demise was placental abruption and uterine rupture, due to maternal blunt abdominal trauma.

PROSECUTION OF THE CASE

I will now discuss the prosecution of Airman Robbins for the attacks on his wife. Any time a commander becomes aware of possible misconduct by a member under his or her command, the commander has the responsibility to review available evidence and decide whether any type of disciplinary action is appropriate. As is typical in cases such as the

Robbins case, Special Agents from the Air Force Office of Special Investigations investigated the incident. After the investigators completed their report they forwarded it to Airman Robbins' commander who reviewed the report and consulted with his Staff Judge Advocate, who is the senior legal advisor to the commander. As part of this process, a Judge Advocate reviews the report, determines whether any of Airman Robbins' actions violated the Uniform Code of Military Justice (UCMJ), and makes recommendations on how Airman Robbins' commander should handle the matter. The Judge Advocate's recommendations are strictly recommendations and the commander has the final say in what action, if any, to take.

His commander decided that the incident was serious enough to warrant criminal charges. A Judge Advocate prepared the Charge Sheet, which the commander signed to initiate the criminal prosecution. This step is known as preferral of charges. The convening authority, a commander senior to the commander who preferred charges, determined additional investigation was appropriate. He appointed a Judge Advocate to conduct a pretrial investigation of the charges then pending against Airman Robbins. This Judge Advocate had nothing to do with the case previously, and could not be further involved in the case after the investigation was completed.

The Charge Sheet listed all the offenses that Airman Robbins' commander had reason to believe he had committed. Offenses under the UCMJ are codified in Title 10 U.S.C., Chapter 47. The offenses are either listed in Articles 80 through 132, commonly referred to as the enumerated Articles, or contained in Articles 133 or 134. Article 133 applies to conduct unbecoming an officer, and is not more specifically defined. Article 134 is the general article and includes "disorders and neglects to the prejudice of good order and discipline in the armed forces" (clause 1 offenses), "conduct of a nature to bring discredit upon the armed forces" (clause 2 offenses) and "crimes and offenses not capital" (clause 3 offenses). Clause 3 encompasses the Federal Assimilative Crimes Act (18 U.S.C. Section 13). In this Act, Congress incorporated "state criminal laws for areas of exclusive or concurrent federal jurisdiction, provided federal criminal law, including the UCMJ, has not defined an applicable offense for the misconduct committed" as offenses under the UCMJ.

Airman Robbins was initially charged with two specifications (counts) of assault against Mrs. Robbins under Article 128 of the UCMJ; maiming under Article 124 by rupturing her uterus with repeated punches to her abdomen with his fist; and with murder and involuntary manslaughter under the Assimilative Crimes Act provision of Article 134. The murder and involuntary manslaughter offenses were charged by assimilating an Ohio

statute, the Amended Substitute Senate Bill No. 239, codified in §§2903.02 and 2903.04 of the Ohio Revised Code, that went into effect on 6 September 1996. As this Committee may be aware, this state law created a series of criminal offenses for causing the "unlawful termination of another's pregnancy." The term "unlawful termination of another's pregnancy" was defined as "causing the death of an unborn member of the species homo sapiens, who is or was carried in the womb of another, as a result of injuries inflicted during the period that begins with fertilization and that continues unless and until live birth occurs." Ohio Revised Code §2903.09(A).

The court determined that, since there is no comparable UCMJ offense, the state law could be assimilated into the federal law and could be prosecuted under Article 134 of the UCMJ.

After the pretrial investigation the Investigating Officer prepared a report that was forwarded through command channels, and the charges were ultimately referred to a general court-martial on 16 October 1996. A general court-martial is the highest court-martial forum in the military. It can adjudge any authorized punishment up to and including death. The trial was held on 9 December 1996, and Airman Robbins asked to be tried by military judge alone. At trial, the maiming charge was merged with one of the assault charges and Airman Robbins pled guilty to assaulting his

wife. He also pled guilty to involuntary manslaughter by causing the unlawful termination of his wife's pregnancy. The murder charge was dismissed, pursuant to a pretrial agreement, the military equivalent of a plea bargain. The military judge sentenced Airman Robbins to be dishonorably discharged from the Air Force, to be reduced to the grade of E-1 (the lowest enlisted grade from his previous grade of E-2) and to be confined for 8 years.

Airman Robbins' conviction has been reviewed and upheld on appeal by the Air Force Court of Criminal Appeals. We are awaiting a decision by the U.S. Court of Appeals for the Armed Forces on his appeal to that court.

Testimony of

RONALD WEICH

Zuckerman, Spaeder, Goldstein, Taylor & Kolker, L.L.P.

Former Special Counsel, U.S. Sentencing Commission

before the
Subcommittee on the Constitution
of the House Committee on the Judiciary

on H.R. 2436, the "Unborn Victims of Violence Act"

July 21, 1999

Mr. Chairman and members of the Subcommittee: My name is Ronald Weich and I am a partner in the law firm of Zuckerman, Spaeder, Goldstein, Taylor & Kolker. I am pleased to appear before you today to discuss the criminal law and sentencing implications of H.R. 2436, the "Unborn Victims of Violence Act."

I bring several qualifications to this task. From 1983 to 1987 I worked as an Assistant District Attorney in New York City, where I prosecuted a wide array of criminal cases. Thereafter I served as Special Counsel to the United States Sentencing Commission and participated in drafting amendments to the federal sentencing guidelines. I then served on the staff of several Senate committees where I assisted in the development of federal crime and sentencing policy. I am now in private practice, but I continue to serve on the advisory board of the Federal Sentencing Reporter, a scholarly journal in which I have frequently published articles on sentencing law and policy. I am also a member of the Criminal Justice Council of the American Bar Association.*

After reviewing H.R. 2436 in light of my experience in the criminal justice system, my knowledge of the federal sentencing guidelines and an examination of relevant case law, I reach one basic conclusion: *this bill is unnecessary.* Current federal law provides ample authority for the punishment of criminals who hurt fetuses. H.R. 2436 adds nothing meaningful to the charging arsenal of federal prosecutors or the sentencing options available to federal judges.

---

* I wish to make clear that I am not testifying on behalf of the American Bar Association or any other entity with which I am affiliated. Nor am I testifying on behalf of any of my law or lobbying clients. For example, it is a matter of public record that I have represented Planned Parenthood Federation of America (PPFA) with respect to pharmaceutical pricing issues, but I do not represent PPFA at this hearing. The views I express herein are strictly my own.

Because the bill is unnecessary from a criminal law perspective, I suspect that its purpose, instead, is to score rhetorical points in the never-ending struggle over abortion rights. But for reasons that I will explain, I strongly object to the use of the federal criminal code as a battlefield in the abortion wars.

I will first describe why the bill is unnecessary in light of current federal law and then explain why I believe it is an unwise addition to federal law.

I. H.R. 2436 IS UNECESSARY.

Current federal law already provides sufficient authority to punish the conduct that H.R. 2436 purports to punish.

At the outset it should be understood that very few violent crimes are prosecuted in the federal courts. Most street level violent crimes are prosecuted under state law by state prosecutors in state courts. Under our constitutional system, federal criminal jurisdiction only exists if the crime implicates federal civil rights or interstate commerce – which few violent crimes do – or if the crime occurs on a federal enclave such as a federal office building, a military base or an Indian reservation. Thus there are only a handful of federal murder and assault prosecutions each year, and most of those involve Native Americans.

H.R. 2436 targets relatively rare conduct to begin with, namely criminal assault on a fetus. And in the federal context, that rare conduct is even more unusual. I researched federal case law and found only one reported case in recent years in which the victim of the offense of conviction was a fetus. In that case, US v. Spencer, 839 F.2d 1341 (9th Cir. 1988), the Native American defendant assaulted a pregnant woman on an Indian

reservation, kicking and stabbing her in the abdomen. The woman was successfully treated for life-threatening injuries, but her fetus was born alive and then died. The Ninth Circuit upheld the defendant's conviction under the federal murder statute, 18 U.S.C. § 1111. Thus, even without the help of H.R. 2436, a federal defendant was successfully prosecuted for murdering a fetus.

The Spencer decision is significant for several reasons. First, it illustrates how rare such cases are in the federal system -- the court refers to the issue of federal criminal liability for fetal death as one of "first impression" and in the 11 years since it was decided, Spencer has never been cited by another court. While there may be isolated incidents that can be addressed under existing federal or state law, there is no crime wave of federal fetal assaults crying out for a legislative solution. But even should this rare scenario present itself in federal court again, Spencer stands for the proposition that criminal liability may be imposed under current federal statutory provisions. The Spencer court relies on the well established common law doctrine, developed in state courts, that fetal death subsequent to birth due to fetal injuries may be prosecuted as homicide. See, Annotation, Homicide Based on Killing of Unborn Child, 64 A.L.R. 5th 671 (1998).

Analytically separate from the question of criminal liability is the question of punishment. Here again, *current federal law is sufficient.* There is no dispute that causing harm to a fetus during the commission of a federal felony should generally result in enhanced punishment, and courts have uniformly held that such enhancements are available under the current sentencing guidelines. For example, in both U.S. v. Peoples, 1997 U.S. App. LEXIS 27067 (9th Cir. 1997) and U.S. v. Winzer, 1998 U.S. App. LEXIS 29640 (9th Cir. 1998), the court held that assaulting a pregnant woman during a bank robbery could lead to a two level enhancement (approximately a 25% increase) under

§ 2B1.1(b)(3)(A) of the Guidelines relating to physical injury. In U.S. v. James, 139 F.3d 709 (9th Cir. 1998), the court held that a pregnant woman may be treated as a "vulnerable victim" under § 3A1.1 of the Guidelines, again leading to a two level sentencing enhancement for the defendant. And in United States v. Manuel, 1993 U.S. App. LEXIS 14946 (9th Cir. 1993), the court held that the defendant's prior conviction for assaulting his pregnant wife warranted an upward departure from the applicable guideline range for his subsequent assault conviction.

While there have been no federal death penalty prosecutions of civilians in recent years involving fetal assaults, the military justice system treats the murder victim's pregnancy as an aggravating factor to be considered during the capital sentencing phase of a trial. United States v. Thomas, 43 M.J. 550 (US Navy-Marine Corps Ct. of Crim. App. 1995). This holding follows state law precedents in which the pregnancy of the victim is a statutory aggravator in capital cases. See, e.g., Del. Code Ann. Tit. 11, § 4209(e)(1)(p) (Supp. 1986).

The federal cases that already treat fetal injury as a relevant factor for establishing criminal liability or enhancing the defendant's sentence are consistent with a much larger body of state cases. Indeed, these state cases, which the Ninth Circuit relies on in Spencer and which are comprehensively collected at Annotation, *Homicide Based on Killing of Unborn Child*, 64 A.L.R. 5th 671 (1998), reveal that the issue of criminal liability for fetal injury is one that Anglo-American law long ago addressed and resolved in a common sense way. Several states, such as Georgia and Illinois, have enacted feticide statutes, but in other states the governing common law rule is that assaulting a pregnant woman and thereby causing the death of a viable fetus gives rise to criminal liability.

In sum, H.R. 2436 is unnecessary because federal case law and the federal sentencing guidelines, building on well-established common law principles, already authorize serious punishment for the harm that the bill seeks to address.

II. H.R. 2436 IS DETRIMENTAL TO THE CRIMINAL JUSTICE SYSTEM.

To say that H.R. 2436 is unnecessary does not end the inquiry. As members of the Judiciary Committee well know, the federal criminal code is characterized by regrettable redundancy, and one more criminal law prohibiting what is elsewhere prohibited would barely add to the thicket. But for three reasons, H.R. 2436 would not only constitute an unnecessary addition to the Code, it would also be an undesirable addition.

First, the bill has been drafted in a structurally unsound manner and will lead to considerable confusion and litigation. To be convicted under 18 U.S.C. § 1841, the new criminal offense created by H.R. 2436, a defendant must have "engage[d] in conduct that violates" one of the existing federal crimes enumerated in § 1841 (b). But must the defendant be convicted of one of those other offenses before he may be convicted of the separate offense under § 1841? I think that is a sound reading of the statutory text, but the language is unclear. There is already considerable controversy and resource-draining litigation in the federal courts over whether various title 18 provisions constitute separate offenses requiring proof beyond a reasonable doubt or sentencing enhancements requiring only proof by a preponderance of evidence, see, e.g., Jones v. United States, 119 S. Ct. 1215 (1999). H.R. 2436 would add to this confusion if there were ever a prosecution under the new criminal provision it establishes.

This problem could be addressed if, instead of creating a new criminal offense, H.R. 2436 merely directed the Sentencing Commission to either establish a new sentencing enhancement when the victim of the crime is a pregnant woman, or make clear that a pregnant woman may be considered a "vulnerable victim" under existing § 3A1.1 of the Sentencing Guidelines. As demonstrated above, the generic provisions of the Guidelines already accomplish this result. But at least a sentencing enhancement bill would not foster confusion and litigation.

Second, H.R. 2436 is overbroad. To begin with, it incorporates by reference an unduly broad definition of "bodily injury" from 18 U.S.C. § 1365. Whereas the common law rule applied to termination of the pregnancy, H.R. 2436 would make it a violation of federal law to cause "physical pain" to the fetus or "any other injury to the [fetus], no matter how temporary." 18 U.S.C. § 1365 (g)(4). That definition may make sense in the consumer safety context from which it derives, but it is bizarre and extreme in the prenatal context of H.R. 2436. Further, H.R. 2436 applies to all fetuses, not merely those that are viable, and applies to unintentional as well as intentional conduct. The common law rule, evolved over centuries of Anglo-American jurisprudence, is that an assault causing the death of a viable (or, in the archaic phrase, "quickened") fetus gives rise to criminal liability. The rule in H.R. 2436 is that an assault unintentionally causing "pain" to a weeks-old fetus gives rise to criminal liability.**

Third, the bill is a transparently rhetorical exercise in the perennial effort to undermine Roe v. Wade. Since H.R. 2436 adds nothing meaningful to substantive federal

** The bill's new § 1841 (d) defines the term "unborn child" tautologically as "a child in utero." Unless the drafters of H.R. 2426 intend the word "child" to imply viability, the bill would apply to conduct that impacted a first trimester pregnancy. Whether an "unborn child" of such gestational age constitutes a human being raises constitutional issues beyond the scope of this testimony.

criminal law, its purpose is purely symbolic: to bestow statutory personhood on fetuses, even those that are not viable.

It is no accident that the bill says nothing about injuries to pregnant women; instead the newly created title is styled "PROTECTION OF UNBORN CHILDREN." An assault on a fetus cannot occur without an assault on the pregnant woman, but the bill is deliberately framed in terms that ignore the woman. To be sure, there is an explicit exception to the criminal penalties in the bill for "conduct relating to an abortion" but make no mistake -- this bill is just one more step in the anti-abortion movement's methodical strategy to humanize fetuses, marginalize women, demonize abortion providers, and make the image of abortion less palatable to the American people. The extreme overbreadth of H.R. 2436 flows directly from that strategy.

The validity of the constitutional protections established in Roe v. Wade exceeds the scope of this testimony and is beyond my field of expertise. But as someone who cares deeply about the integrity of the criminal law, I cringe to see a skirmish in the abortion wars flare up unnecessarily in the federal criminal code. The criminal justice system is built on ancient principles such as proportionality of punishment and the requirement that a wrongdoer have acted with intent to cause harm (mens rea). H.R. 2436, crafted as it apparently was with an eye toward public relations rather than public safety, ignores these principles and thereby corrodes respect for the criminal law as a whole.

Because I believe H.R. 2436 to be both unnecessary and unwise, I urge the subcommittee to reject it.

Statement of Terry Dempsey

Before the Subcommittee on the Constitution
on H.R. 2436, the "Unborn Victims of Violence Act of 1999"

My name is Terry Dempsey, and I want to thank you all for allowing me to appear before this committee to address issues that I feel are important.

As a member of the Minnesota House of Representatives, a similar issue came to my attention, and I felt strongly that it merited a legislative response. What gave rise to the issue was a tragic automobile accident that involved an expectant mother who was operating her vehicle on a normal driving day. Sometime before she could complete her trip, her automobile was involved in a collision. Her car and one being operated by a drunk driver collided. Although the mother wasn't seriously injured, the collision did result in the death of her unborn child. The mother was beyond her sixth month of pregnancy.

Our statutes at the time did not provide for any penalty for someone causing such an injury—in this case the death of the fetus. There was a strong outpouring of sentiment that such conduct should be punishable under our criminal law. Albeit, that civil liability may result, with insurance coverages and other factors coming into play, that did not seem to be an adequate remedy.

Minnesota Statutes were amended by a bill I authored. At the outset there was some discussion that the motives for the legislation was something other than to attach criminal sanctions for such conduct, but the bill passed and became law. There was not a lot of interest in the new law until a case was brought in District Court in northern Minnesota. That charge seemed to generate some questions about my motive and those who voted for the legislation. Was it really wrongful conduct warranting criminal prosecution, or was it a ruse to somehow confer upon the unborn a standing that might lead to other legislation or even court decisions of a similar nature. It even attracted one major news network to come to Minnesota to do a short news story about it on network TV. I was asked in an interview about why the legislation was needed; others were similarly asked the same question. That was a number of years ago. The law remains intact today. Those of us who supported the legislation, and now even some of those who at one time had reservations about the precedent that it might set, agree it wasn't an attempt to erode the Roe v. Wade decision of a person's right to an abortion, but was the right thing to do.

As a lawyer and a judge, I have not seen any attempt to use the law for any purpose, except to punish those who break its provisions. Is it an absolute deterrent to the crimes they address? I can't say. But I can say with some degree of surety

that for those who are affected by the conduct which this Minnesota statute addressed, agree that it closed a glitch in the law that had existed by making such conduct a criminal offense. To defeat the proposal before you based on some fear that this might be a slippery slope and used to "confer" or "attribute" rights to the unborn is contrary to the experience in Minnesota. Our statutes do not deal with the right of abortion, nor do they conflict with the U.S. Supreme Court decisions on abortion. In truth and in fact, the legislation in Minnesota addresses the conduct of a person as it affects the lives of others and hasn't been expanded beyond that by our courts, nor have I seen any attempt that it be used for other purposes.

As you consider the proposal before you, I hope you will look to the Minnesota experience as a precedent. The legislation is similar, and the reasons for passage are evident. The reason for opposing this legislation I feel cannot be on the merits of the proposal, but rather a feeling that there might be some side effects that some may attempt to use this legislation for purpose beyond the sanctions attached to a criminal act. I doubt that such attempts would be successful based upon what has occurred in Minnesota. There is clearly a wrong to be addressed by the bill you are considering.

Thank you again for letting me discuss my feelings and experiences with you.

Prepared Statement of Hadley Arkes,
Ney Professor of Jurisprudence and
American Institutions, Amherst College
Hearings for the Subcommittee on the Constitution
House Committee on the Judiciary
July 21, 1999

Chairman Canady, Members of the Committee:

My name is Hadley Arkes. I am currently the Edward Ney Professor of Jurisprudence and American Institutions at Amherst College. I've taught at Amherst for the past 33 years, with the exception of several years in which I have been in Washington on leave and visiting at places like the Brookings Institution, the Woodrow Wilson Center at the Smithsonian Institution, and Georgetown University. My main interests as a writer and a teacher have been focused on political philosophy, public policy, and constitutional law. I have written, in that vein, several books, published by Princeton University Press, including The Philosopher in the City (1981), First Things (1986), Beyond the Constitution (1990), and The Return of George Sutherland (1994). My principal concerns in recent years have been with the so-called "life issues," of abortion and euthanasia, and if it suits the Committee I can append a list of my publications bearing on those issues.

I am here today to testify on behalf of HR 2436, a bill titled as the "Unborn Victims of Violence Act of 1999." It might be said of this bill what Lincoln said of that rather moderate and modest bill he proposed to encourage the gradual and compensated removal of slavery: that it would come "gently as the dews of Heaven, not rending or wrecking anything." The bill does not seek to extend the federal jurisdiction; it achieves its end mainly by filling out the authority that is already in place. The bill is so carefully cabined or limited that it reaches only the killings that are committed in the course of crimes that clearly fall now within the jurisdiction of the federal government. That question, of what the federal jurisdiction reaches, has been one of the most maddening and vexing questions in our law, and it seems to me bound up with some of the insoluble problems of a national government professing at the same time to be the government of a federal republic. It was only within our own lifetimes that it was thought appropriate to bring forth a distinct federal authority to prosecute for the murder of a president of the United States. We ought to recall that, if Lee Harvey Oswald had gone on trial, he would have been tried for a homicide under the laws of Texas. We ought to recall, too, that there were plausible arguments against the need or justification for that extension of authority, just as there were plausible arguments in the Supreme Court, at the turn of the century, as to whether the federal government could act distinctly to protect justices of the Supreme Court who were threatened or assaulted. [See In re Neagle, 135 U.S. 1 (1890)] And if there were plausible arguments on those points, it was all the more problematic when the federal statutes were extended to cover the assault by private persons on private citizens, holding no office. But a

generation ago, the murder of three Civil Rights workers in the South, by thugs allied with a local sheriff, brought us past another threshold here in our understanding of the federal jurisdiction. [*U.S. v. Price*, 383 U.S. 977 (1966).]

Without the crossing of that threshold, in the cases on civil rights, it would be hard to account for the accumulation of statutes since that time, extending the federal authority to cover drive-by shootings in cases dealing with drugs, or acts of intimidation by private persons who might be obstructing the access to abortion clinics. It would be rather late in the day, then, to invoke concerns about "States' rights" and raise an earnest question about the reach of the federal government in these cases. Nor would it be apt to argue that acts of fetal homicide could be covered already under local law, since in virtually all of these other cases, the crimes were already covered by local law. The argument for a federal law had something to do with teaching new lessons about the seriousness of the crime by raising it to the level of a federal offense. That is the only plausible account that may yet be given about the need for the federal government to be addressing "hate crimes" and "sexual harassment." In order to oppose the current bill, it seems to me that one would have to begin by arguing that the federal jurisdiction was wrongly extended in any these statutes that provide the "predicate" for this bill.

Those kinds of arguments may always be in season, but even if we changed our minds, say, on the matter of drive-by shootings over drugs [18 U.S.C. Sec. 36], that would not affect the substance of this bill. For this bill seeks to follow, closely, the contours of the federal jurisdiction. Its framers seem content to focus only on the matters clearly within the reach of the federal government, and for them that is already an important scaling down in the name of moderation. Even if we repealed the statutes on drive-by shootings, or the protection of access to abortion clinics, the bill would simply apply to the domain of federal jurisdiction that remained. Presumably, the federal government would continue to bear a distinct responsibility, say, for crimes committed within the military. And so this bill could bear, with a dramatic relevance, on the recent case of an enlisted man in the air force who beat his wife and caused the death of the child she was carrying (*U.S. v. Robbins*, argued before the Court of Appeals for the Armed Forces in May, 1999).

In that case, Gregory Robbins was charged with several offenses, but prosecutors for the Air Force did not think they could charge him for the killing of the unborn child who had already been given the name of Jasmine. For cases of this kind, this bill would make a profound difference. But again, it would not make that difference by extending the federal jurisdiction into new domains. Its "novelty," if we could call it that, comes by only by extending the protections of life to the innocent human being who is present on the scene, but covered in her mother's womb. Yet, that is to say, the federal law would be filled out by adding what we should have understood to have been there all along. For we would simply adjust the federal law more precisely to the understanding of the Founders, as reflected, for example, in James Wilson, one of the framers of the Constitution and a member of the first Supreme Court. In his first lecture on jurisprudence in 1790, Wilson reminded his audience that the purpose of the government was to secure and enlarge our "natural rights," and if there were natural rights, the question was, When

did they begin? Wilson's answer was that they began as soon as we ourselves began to be:

> In the contemplation of law, [wrote Wilson] life begins when the infant is first able to stir in the womb. By the law, life is protected not only from immediate destruction, but from every degree of actual violence, and, in some cases, from every degree of danger. [James Wilson, "Of the Natural Rights of Individuals," in The Works of James Wilson (Cambridge: Harvard University Press, 1967; originally published in 1804), Vol. 2.]

This understanding is, of course, quite unsettling to the partisans of the "right to abortion," and yet this bill rests on premises that even the proponents of "choice" on abortion have been compelled to accept. In prominent articles in recent years, "pro-choice" writers like Naomi Wolff and Camille Paglia have insisted that the pro-choice argument cannot plausibly begin with the claim that we have any doubts about the species, or the human standing, of the child in the womb. If we did not know that there was indeed a child there, the problem of an "unwanted pregnancy" would dissolve. If that organism was a bird or an orange, there is less moral difficulty in disposing of an unwanted bird or orange. But beyond that, the proponents of "choice" have supported the actions to prosecute, or recover damages, for the injuries done to unborn children. Where pregnant women have decided to carry their pregnancies to term, where their children in the womb are regarded as babies, wanted by their mothers, the proponents of choice seem to have been obliged, by their own principles, to recognize the standing of those unborn children as human beings in utero, whose injuries then have standing in the law.

From that perspective, this current bill offers nothing that need be unsettling to the proponents of "abortion rights." And in fact, the bill makes it clear, in two places, that it does not threaten *Roe v. Wade*, or call into question the "right to abortion." That must be taken as a sign of the prudence shown by the drafters of the bill: They knew that they would be inviting a sweeping rejection of this measure in the courts if this bill were thought to be a device for making a nullity out of *Roe v. Wade*. But for the same reason, it should be understandable that this bill would raise concerns among those of us who have sought to extend the full protections of the law to unborn children. It certainly must stand as an exemplary awkwardness here that the law would protect the right of a woman to destroy her unborn child, but that if she is assaulted on the way into the abortion clinic, she could then sue for damages that may be done to that same child! The problem, for some of us, can be crystallized in this way: The bill could have been written only in its current form, with its explicit acceptance of *Roe v. Wade*; and yet, the law cast in that way threatens to confirm the deeper premises of *Roe v. Wade* --namely, that the child bears no intrinsic dignity in herself, as a human being with a claim to the protections of the law. The child will be protected by federal law only if her existence accords with the interests or convenience of her mother. She is protected by the law only if the mother is pleased to have her live.

Why, then, should this bill be supported by those people who are styled "pro-life"? I would suggest that this bill has a mix of properties we have seen only in rare cases: there is the

most limited reach of the bill, staying closely to the contours of what the law permits. but at the same time, as everyone can sense, the bill draws on an understanding of principle running deep. The bill is carefully limited, but at the same time it plants, in the federal law, the premise that unborn children are indeed beings of jural standing--beings who can receive the protections of the law; and that the authority of Congress does in fact reach to the protection of unborn children, at the very least, in the places where the federal government can now reach. The protection of federal law is not confined to "citizens," or "residents" or "inhabitants," because it may extend to aliens or visitors. And it is not confined to "persons" because it may be extended to cover animals or "endangered species." It is hardly a stretch then for the law to encompass, in its protections, those human beings who are as yet strangers because they have not yet left the womb--but whose faces and features may be known already to their parents and families through sonograms.

On the other side, the people who style themselves "pro-choice" may find consolation in the fact that the law has lived now, for many years, with contradictions of this kind, without undoing the right to abortion. Several years ago a judge in Washington, D.C. confined a woman in prison because, as a "crack" addict, she was endangering her unborn child. The irony, however, quite hard to miss, was that this woman could not have been divested of her constitutional "right" to an abortion; and so at any moment she could have removed the very ground of her incarceration by ordering up the surgery that would have removed, in a stroke, the object of the court's concern. In other parts of the law, we have seen unborn children in the womb invested with "standing" in courts as the inheritors of legacies, or as victims, with a claim to recover against negligent drivers. That is to say, our law has remarkably managed to preserve itself in this world of assumptions radically in conflict: On the one hand, the child in the womb is treated as a victim, with standing in the law to vindicate its injuries. On the other hand, when a woman elects an abortion, that same child is regarded as a legal nonentity, with no standing, or no "injuries" that the law can recognize. The opponents of this bill no doubt suspect that the intention of the law is lend just a bit more weight to the parts of the law that seek to protect the child. The current bill, H.R. 2436, simply reflects the anomalies that run through the law, and it can do nothing itself to dissolve them. But the bill also works to remind the partisans of "choice" on abortion that they too, in many ways, affirm their understanding that there is nothing other than a human being, a small child, in the womb; and it may put the question to them, with a gentle but wholesome strain, of just how long they can preserve the fiction for themselves that they don't know what is in the womb, or that killing is taking place.

For those of us on the other side, the bill bears the promise of teaching something and lending a certain added, moral weight to the parts of the law that seek the protection of the child. Still, it is worth cautioning again that this bill would protect only those unborn children somehow caught up in those actions marked off, with clear boundaries, as federal crimes. It goes without saying that these unborn children are not the objects of intimidation, say, in preventing people from voting, serving on juries, filing claims under federal law. They may be only the closest relatives or people suffering those assaults, or they may be the victims of collateral damage. But here they are covered by the axioms of the law: If the federal government

can protect presidents and congressmen, that authority must extend to those who would assault presidents and congressmen by assaulting their relatives or taking them hostage. If a person has no "right" to engage in shooting at a Post Office, he cannot be curiously insulated from any charges of wrongdoing, under the same statutes, if he happens to kill innocent bystanders.

My own hope is that the significance of this legislation may be enlarged, or come to its fuller meaning, when unborn children can become in themselves the objects of federal protection: The deprivation of "life" without due process of law, already contained in the Constitution, could be understood, once again, to apply to all human beings, as it was understood at the time of our Founding.

Yet, as everyone knows, we are distant from that state of affairs right now. We can make a first step in that direction only when the Congress is able to establish, finally, that there is some limit on the right to abortion, even at the point of live birth. In my own judgment, the bill before us today would reach its fuller significance when Congress resumes its effort to put in place those premises, running even deeper yet.

But that for another day; I don't mean to mix my missions. I am here today to support this bill, which in itself, in its own limited compass, accomplishes a profound good. For this modest measure may actually succeed in saving lives, and so I'd rework a line of Lincoln's and say--as he once said of another modest measure, running deep--may the vast future not have to lament that we have neglected to do this modest, but telling thing.

Hadley Arkes
July 1999

NATIONAL COALITION AGAINST DOMESTIC VIOLENCE
Every Home A Safe Home

July 21,1999

Good afternoon. My name is Juley Fulcher and I am the Public Policy Director of the National Coalition Against Domestic Violence. The National Coalition Against Domestic Violence is a nationwide network of approximately 2,000 domestic violence shelters, programs and individual members working on behalf of battered women and their children. My role here today is to advocate for increased safety for battered women, which in turn will lead to healthier pregnancies and births. Unfortunately, the "Unborn Victims of Violence Act" does NOT provide the protection that battered women need to obtain safety.

Historically, one of the major obstacles to eradicating domestic violence from the lives of women has been the unwillingness of the legal system to treat domestic violence as a serious crime. The hard work of dedicated domestic violence advocates on the front lines has slowly brought about a change in the way we treat the crime of domestic violence. States began toughening laws on domestic violence and enforcing existing laws in the late 1980s. In 1994, Congress gave an important boost to this trend by passing the Violence Against Women Act and committing to a federal investment in protecting battered women and their children. As a result, we have seen increased criminal prosecutions of domestic violence nationwide. It is important that we continue this trend and recognize domestic violence threats, assaults and murders as the serious crimes that they are.

According to a 1994 report from the Centers for Disease Control and Prevention, at least 6% of all pregnant women in this country are battered by the men in their lives. As an attorney representing victims of domestic violence, I have seen the effects of this violence first hand. Several years ago, a client of mine lost a pregnancy due to domestic violence. While she was 8 months pregnant, her batterer lifted her up in his arms and held her body horizontal to the ground. He then slammed her body to the floor causing her to miscarry. No matter how many

119 Constitution Avenue NE Washington, DC 20002 ● Phone 202-544-7358 ● Fax 202-544-7893 ● ncadv2@sprynet.com

stories like this I hear, it never ceases to sicken me. I should note that in this case and others I have worked on, it was clear by the batterer's words and actions that his intent was to cause physical and emotional injury to the woman and establish undeniably his power to control her. We, as a society, are right to want to address this problem and protect women from such a fate. However, our response to the problem should be one that truly protects the pregnant woman.

The "Unborn Victims of Violence Act" is not designed to protect women. The goal of the Act is to create a new cause of action on behalf of the unborn. The result is that the crime committed against a pregnant woman is no longer about the woman victimized by violence. Instead the focus often will be switched to the impact of that crime on the unborn fetus, once again diverting the attention of the legal system away from domestic violence or other violence against women.

Moreover, passage of the "Unborn Victims of Violence Act" would set a dangerous precedent which could easily lead to statutory changes that could hurt battered women. This bill would, for the first time, federally recognize that the unborn fetus could be the victim of a crime. It would not be a large intellectual leap to expand the notion of unborn fetus as victim to other realms. In fact, some states have already made that leap and, in those states, women have been prosecuted and convicted for acts that infringe on state recognized legal rights of a fetus. While the "Unborn Victims of Violence Act" specifically exempts the mother from prosecution for her own actions with respect to the fetus, it is easy to imagine subsequent legislation that would hold her responsible for injury to the fetus, even for the violence perpetrated on her by her batterer under a duty to protect theory. Moreover, a battered woman can be intimidated or pressured by her batterer not to reveal the cause of her miscarriage and, if she is financially or emotionally reliant on her batterer, may be less likely to seek appropriate medical assistance if doing so could result in the prosecution of her batterer for an offense as serious as murder. The long-term public health implications of such a policy would be devastating for victims of domestic violence and all women.

The harmful potential of this bill is, unfortunately, balanced by little or no additional protections for battered women and other women victimized by violence. The vast majority of domestic

violence threats, assaults and murders -- like other crimes of violence -- are prosecuted by the states. While important federal laws exist to prosecute interstate domestic violence and interstate violation of a protection order, these are stop-gap statutes which are appropriately applied in a very small number of cases relative to the incidence of domestic violence nationwide. In fact, the federal domestic violence criminal statutes have been called into play less than 200 times in the last four years. As the "Unborn Victims of Violence Act" would only apply in federal cases, the change in the law would do little, if anything, to address the crime of domestic violence in our country or other assaults on pregnant women.

I hope you agree with me that the crime of domestic violence is a horrendous one, not only in terms of the physical impact of the violence, but also in terms of its emotional, psychological, social and economic toll upon its victims. Certainly, there can be no doubt that a pregnancy lost due to domestic violence greatly increases that toll on a battered woman. We at the National Coalition Against Domestic Violence wish to fully recognize and respond to that loss. However, the more appropriate means of dealing with this problem with respect to battered women is to provide comprehensive healthcare, safety planning and domestic violence advocacy for victims. This solution would maintain the focus of any criminal prosecution on the intended victim of violence -- the battered woman -- and make an important affirmative step toward providing safety for her. If Congress wishes to protect the pregnancy, the way to do that is by protecting the woman.

File: RU-486

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P00-19
September 28, 2000
FOR IMMEDIATE RELEASE

FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6250
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

FDA APPROVES MIFEPRISTONE FOR THE TERMINATION OF EARLY PREGNANCY

The Food and Drug Administration today approved mifepristone (trade name Mifeprex) for the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the last menstrual period.

Under the approved treatment regimen, a woman first takes 600 milligrams of mifepristone (three 200 milligram pills) by mouth. Two days later, she takes 400 micrograms (two 200-microgram pills) of misoprostol, a prostaglandin. Women will return for a follow-up visit approximately 14 days after taking mifepristone to determine whether the pregnancy has been terminated.

Because of the importance of adhering to this treatment regimen, each woman receiving mifepristone will be given a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side

-More-

effects can occur.

"The approval of mifepristone is the result of the FDA's careful evaluation of the scientific evidence related to the safe and effective use of this drug," said Jane E. Henney, M.D., Commissioner of Food and Drugs. "The FDA's review and approval of this drug has adhered strictly to our legal mandate and mission as a science-based public health regulatory agency."

FDA based its approval of mifepristone on data from clinical trials in the United States and France.

The labeling for mifepristone emphasizes that most women using the product will experience some side effects, primarily cramping and bleeding. Bleeding and spotting typically last for between 9 and 16 days. In about one of 100 women, bleeding can be so heavy that a surgical procedure will be required to stop the bleeding.

The drug's labeling also warns that it should not be used in women with the following conditions:

- Confirmed or suspected ectopic ("tubal") pregnancies
- Intrauterine device (IUD) in place
- Chronic failure of the adrenal glands

- Current long-term therapy with corticosteroids
- History of allergy to mifepristone, misoprostol or other prostaglandins
- Bleeding disorders or current anticoagulant (blood-thinning) therapy.

Under the terms of the approval, mifepristone will be distributed to physicians who can accurately determine the duration of a patient's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding -- or they must have made plans in advance to provide such care through others.

To gather additional data about the use of mifepristone, the Population Council (sponsor of the product) has made a commitment to conduct postmarketing studies. These include a study comparing patient outcomes among physicians who refer their patients needing surgical intervention, compared to those who perform surgical procedures themselves; an audit of prescribers that will examine whether patients and their physicians are signing the patient agreement and placing it in the patient's

medical record, as required; and a system for surveillance, reporting and tracking rare ongoing pregnancies after treatment with mifepristone in the U.S.

Mifepristone, which was developed by a French pharmaceutical firm, was first approved for use in France in 1988. Since then, more than 620,000 European women have taken mifepristone in combination with a prostaglandin to terminate pregnancy. The drug has also been approved in the United Kingdom, Sweden, and other countries.

Mifepristone will be distributed in the U.S. by Danco Laboratories, LLC, New York, N.Y.

More detailed information about this product is available on FDA's website at http://www.fda.gov/cder/drug/infopage/mifepristone/

###

Draft 09/28/00
INTERNAL USE ONLY

Questions and Answers on Mifepristone: INTERNAL USE ONLY

General

Q: What action did FDA take today?

A: Today, FDA approved mifepristone (trade name Mifeprex) for the termination of early pregnancy. The drug is approved to end pregnancies of 49 days or less, counting from the beginning of the last menstrual period.

Q: What treatment regimen did FDA approve?

A: The drug (mifepristone) is administered to a woman by mouth. Two days later, the woman returns to her doctor for oral administration of misoprostol, a prostaglandin that helps cause uterine contractions. Patients will return for a follow-up visit approximately 14 days after taking mifepristone to determine whether the pregnancy has been terminated.

Q: What is the basis for FDA's approval of this regimen?

A: FDA based its approval of mifepristone on data from clinical trials in the United States and in France.

Q: How effective was the regimen in clinical trials?

A: In the U.S. trials, medical termination of pregnancy was complete in 92% of the 827 women in the efficacy study – approximately six percent with mifepristone alone, and the remainder with mifepristone followed by misoprostol. In eight percent of patients, surgical intervention was required. Fewer than 1% of patients had ongoing pregnancies.

In the French trials, more than 95% of the 1,681 women experienced complete termination of pregnancy, 5.3% without misoprostol and the rest after taking both drugs. Surgical intervention was required in 4.5% of women.

Q: Is this the first drug approved in the U.S. for the termination of pregnancy?

A: No. Two other drugs are approved for the termination of pregnancy.

Restrictions

Q: What restrictions did FDA place on the use and distribution of this drug?

A: The drug may only be distributed to physicians who can accurately determine the duration of a woman's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding – or they must have made plans in advance to provide such care through others.

FDA approved mifepristone under its "Subpart H" regulations, which specifically allow FDA to establish appropriate controls on the distribution of a drug.

Q: What about distribution?

A: Mifepristone will be distributed directly to qualified physicians. It will not be available through pharmacies or on the Internet.

Q: What decisions has FDA made about labeling this product?

A: FDA is requiring a "black box" warning in the mifepristone labeling for physicians. The "black box" warns that surgical intervention may be necessary and addresses the care patients should receive should such intervention be necessary. In addition, because of the importance of adhering to this treatment regimen, each woman receiving mifepristone will be given a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side effects can occur. This Guide is also referenced in the "black box."

Q: Why did FDA impose these restrictions?

A: FDA always seeks to ensure that the products it approves are used appropriately, so that risks are minimized and benefits are maximized. FDA believes that, for this drug, these restrictions are needed to ensure safe use.

In addition, the agency believes that women should have as much accurate information as possible to make an informed decision about this regimen.

Q: According to FDA regulations, Subpart "H" applies to drugs for serious and life-threatening illnesses. Isn't it overkill to invoke this provision for the mifepristone regimen?

A: The sponsor proposed a restricted distribution system for its product, and the FDA advisory committee that discussed this application in July 1996 also recommended such a system. FDA has concluded that the termination of unwanted pregnancy is a serious condition, and that these restrictions are necessary for the safe use of this drug.

Moreover, mifepristone's distribution is typically restricted in other countries where it has been approved. FDA has concluded that establishing certain controls on the distribution of this drug are needed to help ensure that it is used appropriately.

Q: Has distribution of any other drugs been restricted? What are some examples?

A: The distribution of several other drugs has been restricted to assure that they are used safely. For example:

- Clozapine (Clozaril), a drug used to manage severe schizophrenia, is available only through a registry system that ensures monitoring of certain blood test results prior to the delivery of the drug.

- Transmucosal fentanyl (Oralet), a potent analgesic delivered on a lollipop as premedication in pediatric patients before surgery or before painful procedures, is restricted to certain registered hospitals, and is not available retail pharmacy outlets.

- The manufacturer of trovafloxacin/alatrofloxacin mesylate (Trovan/Trovan-IV) agreed to limit distribution only to hospitals and long-term nursing care facilities.

- Thalidomide (Thalomid) is marketed only under a special restricted distribution program. Under that program, only registered prescribers and pharmacists are allowed to prescribe and dispense the product.

Patients must also be registered and participate in mandatory pregnancy testing prior to receiving the drug.

Q: Why is FDA requiring a physician to be able to provide surgical intervention or to provide a plan for obtaining those services for each woman using mifepristone?

A: Clinical trials and experience in countries where mifepristone is approved have shown that this regimen fails in five to eight of 100 women. Therefore, if the regimen fails and a woman still wants to terminate the pregnancy, a follow-up surgical procedure will be necessary and must be available.

Also, in about one of 100 women, bleeding can be so heavy that a surgical procedure will be required to stop the bleeding.

Q: Will FDA or the manufacturer establish a registry of physicians who have access to mifepristone?

A: Neither FDA nor the manufacturer has any plans to establish a registry of physicians.

Q: How can cancer patients obtain mifepristone?

A: Mifepristone is available for certain cancer patients through a single patient IND. Patients must be treated according to a specified treatment plan. The drug is provided by the Feminist Majority Foundation.

Pressure on FDA:

Q: There have been press reports that the politics of abortion have delayed FDA's action. How does the agency respond to those reports?

A: FDA is a scientific regulatory agency that makes decisions on the basis of science. The agency's review and approval of mifepristone adhered strictly to its legal mandate and mission as a science-based public health regulatory agency.

Q: The average review time for priority drugs is now six months. The sponsor sent FDA its application in March, 1996. Why did this review take so much longer?

A: FDA sent the sponsor an "approvable" letter in September 1996, six months after receiving the application. The letter identified outstanding issues that needed to be resolved before FDA could approve mifepristone. The sponsor responded to those issues in September 1999. FDA issued another "approvable" letter in February, 2000, asking additional questions. The sponsor has now answered those questions.

Q: Some members of Congress have expressed their opposition to mifepristone. Could Congress overturn FDA's decision?

A: It would be unprecedented for Congress to overrule an FDA decision to approve a medical product.

Q: FDA is a regulatory agency in the executive branch of the Federal government. Could a new administration overrule FDA's approval of mifepristone?

A: As an executive branch agency in the Department of Health and Human Services, FDA has bases its judgments concerning medical and public health matters on sound science. FDA based its approval of mifepristone on data from clinical trials in the U.S. and in France. It would be unprecedented for a new administration to overrule an FDA decision to approve a medical product.

Q: Who manufactures and distributes mifepristone?

A: Danco Laboratories, LLC, based in New York City, distributes mifepristone. Neither the Population Council, the sponsor of this product, nor Danco Laboratories has disclosed the identity of the manufacturer.

Q: Why won't FDA disclose the identity and location of the manufacturing site?

A: Because many threats and acts of violence have been directed at persons associated with reproductive rights issues similar to those raised by mifepristone, FDA will not disclose the identity of the manufacturer or the manufacturing site.

Under these circumstances, this manufacturing information is considered confidential commercial information.

Q: Why is FDA withholding the names of its employees who reviewed the new drug application for mifepristone?

A: Because many threats and actions of violence have been directed at persons associated with reproductive rights issues similar to those raised by mifepristone, FDA will not disclose these employees' names. Under these circumstances, this employee information is considered personal privacy information.

The regimen:

Q: How can mifepristone be safely used?

A: Basically, a woman should follow all the instructions for taking the product. First, a woman must read the Medication Guide and sign the Patient Agreement Form.

Day 1: a patient will be given three 200 milligram tablets of mifepristone.

Day 3: a patient must return to determine if expulsion has occurred. (Expulsion is infrequent with mifepristone alone, happening only in five or six percent of cases.) If expulsion has not occurred, the patient will be given two 200 microgram tablets of misoprostol that she will take orally.

Day 14: the patient will return for a follow-up visit. This visit is very important to confirm that a complete termination of pregnancy has occurred.

Q: How did FDA conclude that mifepristone is safe when its use results in the termination of a pregnancy?

A: The sponsor submitted a new drug application to the FDA, seeking the agency's approval to market mifepristone for the termination of early pregnancy. FDA concluded that the results from the clinical trials established that mifepristone is safe and effective for its intended use. In its review and approval of this application, FDA adhered strictly to its legal mandate and mission as a science-based regulatory agency.

Draft 09/28/00
INTERNAL USE ONLY

Q: Why did FDA require a second visit on Day 3, when the product is being studied and used in a U.S. clinical trial without a return visit on Day 3?

A: Mifepristone was approved on the basis of data from clinical trials, designed by the sponsor, in which every woman in the study was required to return to her physician for a second visit. Unless pregnancy termination through the use of mifepristone alone has been confirmed by clinical examination or an ultrasonographic scan, the woman will take misoprostol during this second visit.

A third visit, to confirm that a complete termination of pregnancy has occurred, is also required.

Q: Why can't all physicians prescribe mifepristone?

A: FDA is restricting the distribution of mifepristone to physicians with specific qualifications, such as the ability to diagnose a tubal pregnancy. These restrictions are designed to ensure safe and appropriate use of the product.

Q: Can nurse-practitioners, midwives, or others prescribe mifepristone? Why?

A: Some states allow physicians to supervise other health care practitioners such as certified registered nurse practitioners and nurse midwives, and these states may allow a supervised health care provider to dispense mifepristone.

Q: What about misoprostol? Is the use of misoprostol an unlabeled use?

A: Under the approved treatment regimen, misoprostol is administered on day three to help stimulate uterine contractions. This use of misoprostol is contained in the approved labeling of mifepristone. It is based on the clinical trials for the regimen of the two drugs, which FDA found to be safe and effective for the termination of early pregnancy.

Draft 09/28/00
INTERNAL USE ONLY

Q: The manufacturer of misoprostol just issued a warning to physicians not to use the drug in pregnant women, and there have been press reports that the manufacturer worked with FDA on this warning. How can FDA reconcile this warning with the approval of mifepristone when used with misoprostol?

A: Misoprostol (used alone) is currently approved for use in protecting patients from gastric ulcers induced by certain pain relievers. A women who is or may be pregnant – and who does NOT wish to terminate her pregnancy -- should know that she should not take misoprostol for prevention of gastric ulcers or any other reason.

The "Dear Doctor" letter issued by Searle on August 23, 2000, warns prescribers that misoprostol may cause abortion. It therefore emphasizes that misoprostol is contraindicated for use by any pregnant woman who does not wish to terminate her pregnancy.

As part of the mifepristone-misoprostol regimen, misoprostol is appropriate for use to terminate early pregnancy.

Q: Searle just distributed new labeling for its misoprostol product (Cytotec) that says the product is not approved for abortion. What is FDA's position on this labeling?

A: Now that FDA has approved the treatment plan for the use of mifepristone followed by the administration of misoprostol for the medical termination of intrauterine pregnancy through 49 days of pregnancy, the statement in the Searle label is inappropriate. FDA has asked that it be removed.

Patient Safety and Side Effects:

Q: What are the major side effects of mifepristone?

A: The Medication Guide provides information that women should be aware of concerning the incidence of side effects from administration of Mifeprex. These include cramping and, sometimes, heavy bleeding. After misoprostol administration on Day 3, there may be nausea, vomiting, and diarrhea. Before taking this medication, a woman must be fully aware of what to expect and will have to sign the Patient Agreement form.

Draft 09/28/00
INTERNAL USE ONLY

The problems or side effects that women should be warned about include bleeding or spotting that is likely to occur from 9 to 16 days and that has been reported to last as long as 69 days. Up to eight percent of women may experience some kind of bleeding for 30 days or more. Surgical intervention may be needed to control the bleeding.

Q: What steps has FDA taken to ensure that women are adequately informed about how to use this regimen safely?

A: FDA is requiring that each woman who takes mifepristone receive a Medication Guide that clearly explains how to take the drug, who should avoid taking it, and what side effects can occur.

Each woman taking this drug must also read the Medication Guide and sign the patient agreement form before the drug will be administered.

Q: What if a woman changes her mind?

A: Among the many safeguards FDA has established for this treatment regimen are the requirements that each woman read the Medication Guide for mifepristone and that she also sign the Patient Agreement Form. These safeguards are designed to ensure that every woman knows and understands that this regimen is for the termination of early pregnancy and is committed to that course of action.

FDA and the sponsor have established a program to inform women about this regimen, including the risk of birth defects if the regimen does not end the pregnancy. Women are instructed that surgical termination may be needed, and the Patient Agreement Form certifies that they understand this possibility.

Q: Critics of this drug say it is dangerous to women and fetuses. How does FDA respond?

A: FDA and the sponsor have established a program to inform women about this regimen, including the risk of birth defects if the regimen does not end the pregnancy. Although the data on this risk are very limited, there are several reports in the medical literature of defects after first trimester exposure to prostaglandins, including misoprostol.

Draft 09/28/00
INTERNAL USE ONLY

As of May 2000, 82 cases have been reported in which women with ongoing pregnancies after using mifepristone, alone or followed by misoprostol, declined to have a surgical procedure. Of those, follow-up information is available for 36. Twenty-six of those women experienced live births, and none of the infants had any abnormalities detected at birth. Ten of the women later decided to have a surgical termination, and of those, there was one case of fetal malformation.

Q: Has the sponsor agreed to carry out postmarketing studies of mifepristone?

A: To gather additional data about the use of mifepristone, the Population Council has made a commitment to conduct postmarketing studies. These include a study comparing patient outcomes among physicians who refer their patients needing surgical intervention, compared to those who perform surgical procedures themselves; an audit of prescribers that will examine whether patients and their physicians are signing the patient agreement and placing it in the patient's medical record, as required; and a system for surveillance, reporting and tracking of ongoing pregnancies after treatment with mifepristone in the U.S.

Q: The sponsor of mifepristone has agreed to conduct postmarketing studies involving this drug. Doesn't that mean FDA really thinks the regimen is unsafe?

A: No. It is not at all unusual for sponsors to conduct postmarketing studies on their approved products.

Access:

Q: Who may prescribe mifepristone?

A: The drug will be distributed only to physicians who can accurately determine the duration of a woman's pregnancy and detect an ectopic (or tubal) pregnancy. Physicians who prescribe mifepristone must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding – or they must have made plans in advance for patients to obtain such care through others.

Draft 09/28/00
INTERNAL USE ONLY

Q: Will it be available in pharmacies?

A: No. Mifepristone will be available only through qualified physicians.

Q: What health professionals will have access to mifepristone?

A: Some states allow physicians to supervise other health care practitioners such as certified registered nurse practitioners and nurse midwives, and these states may allow a supervised health care provider to dispense mifepristone.

Q: Will mifepristone be available over the Internet?

A: No. FDA and the sponsor have established a treatment regimen with many safeguards, including the direct distribution of the drug only to qualified physicians.

Q: In 1990 FDA issued an Import Alert that banned the importation of mifepristone into the United States. The drug was listed under several other names. Is that Import Alert still valid?

A: FDA issued this Import Alert because of safety concerns for people taking the unapproved drug without adequate supervision from a health care professional. Now that FDA has approved Mifeprex, the Import Alert has been revised to exempt this specific product from the alert. Formulations of mifepristone not covered by the NDA or by an IND in effect would still be denied entry into the U.S., however.

Q: Has mifepristone been studied for other uses? If so, will those studies continue?

A: Mifepristone is being studied for a variety of uses, because it can block steroid receptors. In particular, it is being investigated as a potential treatment for cancers whose tumors have progesterone receptors.

ADDITIONAL QUESTIONS AND ANSWERS—INTERNAL USE ONLY

Q: Did the White House or Secretary Shalala intervene in FDA's review of mifepristone?

A: No. Neither the White House nor the Secretary were involved in FDA's decision. FDA based its decision on the science.

Q: Earlier this year there were reports that FDA was going to impose severe restrictions on the availability of mifepristone. What changed FDA's thinking?

A: Some early press reports on this issue were inaccurate. When FDA is nearing the end of a product review, give and take between the agency and the sponsor is normal.

Q: President Clinton in 1993 asked Secretary Shalala to see what could be done to expedite the availability of mifepristone. The Secretary in 1994 said that "FDA will do all it can to quickly evaluate mifepristone." What happened? Why did FDA not tell the sponsor until 1996 that mifepristone was "approvable?"

A: Many things had to occur before the FDA could take any action. The sponsor had to obtain patent rights for the drug, and this happened in May, 1994. The sponsor then had to identify a manufacturer for the drug, file an IND with the FDA, and design and conduct clinical studies of the product. Finally, the sponsor had to analyze the data and submit a marketing application to the FDA.

FDA received the new drug application in March 1996. It began reviewing the application immediately, held an advisory committee meeting in July, and issued an "approvable" letter in September 1996.

Q: Who made the decision to approve mifepristone?

A: Many FDA employees contribute to the review and approval of a new product. The "approval" letter FDA sends to the sponsor is typically signed by a senior official.

In the case of mifepristone, FDA is not disclosing the identity of the reviewers and others who reviewed this application.

Q: What about reports that FDA has hired armed guards and heightened security?

A: FDA does not comment on security matters.

External Q[illegible] A[illegible] for FDA's Web Site

1. What is MIFEPREX (mifepristone) [illegible] how does it work?
Mifepristone is a drug that blocks a [illegible] called progesterone that is needed for pregnancy to continue. Mifepristone [illegible] together with another medicine called misoprostol, is used to end an early [illegible] 49 days or less since your last menstrual period began).

2. Is mifepristone approved in any [illegible] countries?
Yes, mifepristone is approved in many [illegible] countries including France, the United Kingdom, and Sweden.

3. Who should not take mifepristone?
Some women should not take mifepristone. Do not take mifepristone if it has been more than 49 days since your last menstrual period [illegible] if you have:

- a tubal pregnancy
- an intrauterine device (IUD) in place [illegible] removed before you take mifepristone)
- problems with your adrenal glands [illegible] near your kidneys)
- been treated with certain steroid medicines [illegible] a long period of time
- bleeding problems or are taking anticoagulant (blood-thinning) drug products
- had an allergic reaction to mifepristone, misoprostol or similar drugs

It is important that you understand the [illegible] follow-up visits with your health care provider and that you have access to a medical facility in case of an emergency.

Mifepristone has not been studied in women who are heavy smokers. Please tell your doctor if you smoke more than 10 cigarettes a day.

4. Is mifepristone distribution restricted?
Yes, mifepristone is supplied directly to doctors who meet certain qualifications. It is not and will not be available in pharmacies. It is not legally available over the Internet.

5. Why are there restrictions for this drug?
Studies of mifepristone were conducted by doctors who had certain qualifications. Both the drug sponsor and the 1996 Reproductive Health Drugs Advisory Committee also recommended that FDA restrict distribution of mifepristone to qualified doctors. FDA has concluded that these restrictions are necessary for the safe use of the drug.

6. What qualifications must doctors have to prescribe mifepristone?
Doctors must have the ability to date pregnancies accurately and to diagnose tubal pregnancies. Doctors must also be able to provide any necessary surgery, or have

made arrangements for any necessary [illegible] must ensure that women have access to medical facilities for emerg[illegible] must agree to other responsibilities, such as dispensing the Medication G[illegible] any adverse events to the sponsor.

7. What authority does FDA have to r[illegible] of a drug?
The law authorizes FDA to approve [illegible] if they have been demonstrated to be safe and effective for use under the c[illegible] recommended in the label. FDA has broad authority to require restrict[illegible] to ensure safe and effective use. FDA's full legal authority to restrict[illegible] is described in more detail in the preamble to agency drug regulations. [illegible] or scanned copy)

8. Can health care providers other [illegible] mifepristone?
Some states allow physicians to supervise [illegible] care practitioners, such as certified registered nurse practitioners and nurse [illegible] these states may allow a supervised health care provider to dispen[illegible]. Health care providers should check their state law provisions.

9. Is there an age restriction for [illegible] pregnancy?
States may set age restrictions on [illegible] if they believe such restrictions are appropriate.

10. Are there studies with mifepristone [illegible] under the age of 18?
Studies to evaluate mifepristone inc[illegible] 18-45.

11. What are the possible side effects [illegible] mifepristone?
Mifepristone treatment will cause va[illegible] In some cases vaginal bleeding can be very heavy. In a few cases, this bleed[illegible] to be stopped by a surgical procedure.

Other possible side effects of the tre[illegible] diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness.

The possible side effects are describ[illegible] Guide. Please read the **Medication Guide (LINK).**

12. What is a Medication Guide?
A Medication Guide contains FDA-[illegible] written especially for patients.

13. Why did FDA develop a Medi[illegible] mifepristone?
FDA determined that a Medication Guid[illegible] for women to be able to use mifepristone effectively and safely. It is [illegible] women to be fully informed about how mifepristone works and about s[illegible] the need for follow-up visits with their health care provider, especiall[illegible] after mifepristone is administered. The Medication Guide will help ensur[illegible] follow the directions for use and that they return to their health care provider [illegible] visits.

Before you receive mifepristone, your [illegible] will provide you with the Medication Guide and ask you to sign a statement (Patient [illegible]) that you have decided to end your pregnancy.

14. Can I become pregnant again [illegible] mifepristone?
You can becomes pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using a birth control method of your choice as soon as your pregnancy ends.

15. Does FDA endorse the use of [illegible]?
FDA does not endorse or promote any [illegible]. The agency evaluates all drug applications submitted by sponsors to determine whether a drug is safe and effective for its proposed indication under the conditions specified in the labeling. This means that the benefits of the drug outweigh its risks. These standards were applied to the new drug application for mifepristone as are applied to all applications.

16. How much will mifepristone cost?
Manufacturers establish prices for prescription drugs. FDA has no jurisdiction over drug pricing.

17. Will insurance companies pay for [illegible]?
Insurance coverage is a decision made by each insurance provider. Please call your insurance company if you have questions.

FACSIMILE

DATE 9/28/00

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Ms. Maria Echaveste

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Kevin Thurm

690-6133

RECIPIENT'S FAX NUMBER ( ) 202-456-1907

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 20

COMMENTS: