

# Diethylstilbestrol and Media Coverage of the “Morning After” Pill

DIANE-DINH KIM LUU

Communicated by: Dr. Brenda Knowles  
*Honors Program*

## ABSTRACT

The Food and Drug Administration (FDA) approves numerous prescription medicines everyday. The public consumes them, because they believe that these drugs will be safe and effective. We know that not all drugs are one hundred percent free of risks from other side effects, but we consume them because the FDA has judged them to be safe. There are times when the FDA does not approve the safety of high-demand drugs quickly enough to please the public and the companies that would like to manufacture the medicines. One example of such a situation involves the “morning after” pill. As a result of public demand, the media has pressured the FDA to speed up the approval of Diethylstilbestrol (DES) for use as a “morning after” pill. The misleading, inaccurate, and incomplete information about the “morning after” pill as delivered by journalists has deceived members of the public and has caused them to put even more pressure on the FDA. This pressure may cause the FDA to give less careful consideration to the risks associated with the disease and may ultimately harm many women’s health. The popularity of DES in 1970s resulted in tragic outbreaks of cancer in both the users of the drug and their children. By presenting only the benefits of DES, the media jeopardizes the health of many more in the future.

## INTRODUCTION

The news media is a powerful force. It has extensive power because it chooses what stories to deliver and how to present them. Reporters and journalists usually provide reliable information about the weather, sports events, and accidental deaths. However, media coverage of new drugs and medicines is not always as complete and accurate as it should be given the tremendous impact that these stories have on public health.

One example of this is recent coverage of the “morning after” pill. News reporters have delivered the message that the “morning after” pill is a safe and effective postcoital contraceptive that prevents pregnancy after unprotected intercourse. The “morning after” pill contains Diethylstilbestrol (DES), a form of synthetic estrogen that does not contain steroids. DES was introduced in Europe in the 1940s and was believed to be an effective way of preventing pregnancy when other contraceptive methods, such as condoms, fail. DES could also be used in cases of rape. Although the U.S. Food and Drug Administration (FDA) had approved the usage of DES for treatments of breast cancer and osteoporosis, it has never approved its prescription as a contraceptive because of safety concerns. Recent media coverage of the “morning after” pill downplayed

these concerns and instead presented the drug as a safe and effective contraceptive that the FDA is reluctant to approve for social rather than medical reasons. News reports described how widespread use of the pill in Europe had lowered the rate of abortions. They included reports of American doctors who believe so strongly in the effectiveness of the “morning after” pill that they prescribe DES for this purpose despite the lack of FDA approval. Reporters interviewed users who claimed that the pill is a miracle. Because of this one-sided coverage, the American public has begun to pressure the FDA to approve DES as a “morning after” pill. The misleading, inaccurate, and incomplete information presented by the media about the “morning after” pill has deceived the public and, if the FDA gives in to public pressure, may ultimately jeopardize the health of millions of women in this country.

## HOW DO DRUGS BECOME MEDICINES?

Most Americans do not realize how much money and time is required to certify the safety and effectiveness of a new drug. According to *Psychopharmacology Update*, on the average, a company spends a total of \$359 million during the typical fifteen year long drug approval process. The process begins in the laboratory

and ends at the pharmacist's counter. This process involves many steps. The new drug must be examined in the laboratory and must later be tested on animals in order to make sure that it will have no unexpected results when it is introduced into a complex biological system.<sup>1</sup> After the compound is proven to be safe in animals, the company then files an Investigational New Drug Application (IND) with the FDA. The FDA has thirty days to disapprove the application; otherwise, it automatically becomes effective. The IND includes the results of the experiments:

How, where and by whom the studies [on humans] will be conducted; the chemical structure of the compound; and how it [is] thought to work in the [human] body; [suggestion of] any toxicity found in the animals studies; and how the compound is manufactured.<sup>2</sup>

After the FDA approves the IND, the company will begin to test the drug on humans. These tests are divided into three phases of clinical trials. Phase I studies how the drug is absorbed, distributed, metabolized and excreted and generally involves twenty to eighty healthy volunteers. This phase also establishes the correct dosage. Phase II studies the drug's effectiveness on approximately 100 to 300 people. Phase III studies adverse reactions and involves more than three thousand patients in hospitals and clinics. If these tests show favorable results, the company analyzes the data and files a New Drug Application with the FDA. The New Drug Application must include all scientific information that has been gathered, and it is usually more than one hundred thousand pages in length. The FDA reviews the New Drug Application for a minimum of six months, but most drug approvals take more than nineteen months.

#### PUBLIC DISAPPROVAL OF SLOW DRUG APPROVALS

Many Americans complain that the FDA takes too long to certify new drugs. By the time a drug has been officially recognized, some people with the targeted disease may have already died. European nations typically approve drugs faster than the United States. This handicaps American companies that must compete against European drug manufacturers. Intense pressure from these companies and the general public has made the FDA realize that it needs to consider changes to its review process.

The FDA has also faced criticism from people like Dr. Jean Paul Gagnon, a director of global economic policy at Marion Merrel Dow, Inc. in Kansas City, who says,

They [the FDA] are very slow and plodding. They have no vested interest in expediting the drug approval process. Bureaucrats fear they might lose their job if they approve something that backfires.<sup>3</sup>

Gagnon suggests that we should hire other experts who will approve drugs quicker than the FDA. He argues that the FDA is currently "overwhelmed, understaffed, has no organization efficiency, and no real incentive to speed up the approval process."<sup>4</sup> In 1995 the FDA had responded to criticism of this sort by hiring an additional three hundred staffers to review new drugs and medical technologies. The FDA also plans to hire another three hundred staffers in order to further increase the speed of the approval process.

According to *FDA Consumer*, the FDA has implemented four initiatives that would accelerate the approval process. One initiative shortens the approval process for "breakthrough" drugs. The second initiative gives priority consideration to drugs which could treat more serious diseases such as cancer and Alzheimers. A third initiative allows the FDA to accept results from animal drug testing that has been conducted in other countries. This initiative has the added benefit of reducing the total amount of animal testing in the world. The fourth initiative allows the FDA to hire outside experts to "review certain routine applications for new drugs and biological materials."<sup>5</sup> David Kessler, the chairman of the FDA, claims that these four initiatives will reduce the entire drug-approval process from the original length of fifteen years to about ten years.

#### THE USE OF DES FOR LIFE THREATENING DISEASES VERSUS USE AS A POSTCOITAL CONTRACEPTIVE

There are several reasons that the FDA has not yet approved the "morning after" pill. First, the need for this drug is not as pressing as the need for treatments for diseases such as cancer and AIDS. Thousands of Americans have died from AIDS and no reliable treatments have been found. Millions of Americans who have contracted HIV will gladly experiment on their own to prove the effectiveness of certain drugs, and because their disease is life-threatening, there is a feeling that they should be allowed to try untested drugs despite the risk of side-effects. Postcoital contraceptives such as the "morning after" pill are in demand as a way to reduce the abortion rate by preventing eggs from implanting in the uterus. But many Americans believe that the use of birth control pills, especially

<sup>3</sup>Gatty, Bob. "Who Would Approve New Drug If There Were No FDA?" *Hospital Formulary* January (1995): page 59.

<sup>4</sup>Ibid.

<sup>5</sup>"Initiatives Speed Access to Drugs." *FDA Consumer* July (1992): page 1.

<sup>1</sup>Beary, John F. III. "How a Drug Becomes A Medicine." *Psychopharmacology Updates* 8(3) (1997): page 1.

<sup>2</sup>Ibid.

those like the "morning after" pill which prevents contraception after intercourse, is immoral. As a result, there is less public support for the approval of this drug than for other drugs. In addition to these factors, the side-effects and long term consequences of the use of DES as a contraceptive are not yet well understood. While some treatments involving DES seem to be safe and effective, harmful long term consequences such as cancer have been linked to other uses of DES.

One example of a positive use of DES is as a treatment of postmenopausal osteoporosis. According to *Health* journal, Eli Lilly filed a new drug application in 1996 asking for permission to market Raloxifene to treat this condition. The company did experiments in clinics on twelve hundred postmenopausal women from the ages of forty-five to sixty-five. Seventy-five percent took Raloxifene and twenty-five percent took a placebo. The study found that women who took Raloxifene increased their bone density by an average of two to three percent, while those who took the placebo lost bone density. The study also showed that the drug can be used to fight the number one killer in America - heart disease. Raloxifene is now proving its effectiveness in 7,700 women aged sixty to seventy in over twenty countries worldwide. Side effects, such as blood clots in the legs, hot flashes, et cetera, occurred more frequently among those who took the placebo than among those who took the drug. The quest for a cure for osteoporosis may be over. Many treatments for osteoporosis increase the risk of breast cancer, but Raloxifene does not seem to do so. Ethel Siris, director of the osteoporosis program at Columbia-Presbyterian Medical Center in New York, stated that "Raloxifene will give you a bone benefit that's quite substantial . . . it's going to lower bad cholesterol, raise good cholesterol, though not as much - but it's going to do nothing to the uterus. You won't bleed or have malignant changes, and it does not create breast problems."<sup>6</sup> Raloxifene has been on the market as of January 1998 under the brand name Evista. In addition to Evista, many other drugs used to treat osteoporosis contain 0.625mg of estrogen (in the form of DES), "which helps to prevent menopausal symptoms and helps keep women's hearts healthy."<sup>7</sup> For the "morning after" pill to be effective, it must be taken for three to five days after intercourse. This is a very short period of time compared with the several years of use required for the treatment of osteoporosis.

Millions of women increase the estrogen [or a drug containing an estrogen substitute] in their bodies when they take oral contraceptives or pills to relieve symptoms associated with menopause, such as hot flashes, sweating, and vaginal dryness.<sup>8</sup>

The FDA had long since approved many drugs like Premarin, Ogen, and Estrace to treat women and men who suffer from osteoporosis before putting DES on the market as a postcoital contraceptive that is only for emergency use. Droloxifene, Idoloxifene and GW5638 are currently undergoing clinical trials to test their effectiveness in treating both osteoporosis and breast cancer patients. It will be several years before these drugs are proven safe and are available to patients who currently suffer from osteoporosis and breast cancer.<sup>9</sup>

In 1997, the American Public Health Association formally protested the slowness of the FDA approval process for the "morning after" pill which had been pending for over two years. The FDA later endorsed the postcoital contraceptive, indicating that two tablets should be administered seventy-two hours after intercourse and two more in the next twelve hours. Six different brands of oral contraceptives containing ethinyl estradiol and norgestrel (protesgin) or levonorgestrel could be approved as a "morning after" pill.<sup>10</sup> The FDA finally approved DES in the form of the "morning after" pill saying it is seventy-five percent effective and common side effects include nausea, vomiting, bleeding, and breast tenderness.

#### FACTS ABOUT DIETHYLSTILBESTROL

Diethylstilbestrol is a synthetic estrogen that was first introduced in 1938 by Professor E.C. Dodds in Europe. In the 1940s, European doctors tested the pill in one patient, which involved a dosage of 135mg per day for three weeks. It was observed that 150mg of the pill was excreted from the urine within twenty-four hours after ingestion. This quantity of estrogen intake is more than the natural amount of estrogen produced in the body. The findings concluded that DES, used in the prevention of miscarriages, is to be taken "30mg daily with the daily dosage increased by 5mg weekly through the 35<sup>th</sup> week."<sup>11</sup> To prevent miscarriages, the original indication administered a quantity that ranged from 135 to 18,200 mg of DES. In the early 1970s DES was found to cause cancer in animals. Despite the risk of cancer and other complications, doctors still prescribed DES to women around the world to prevent miscarriages throughout the 1970s.

In spite of the carcinogenicity of lower doses of DES and the FDA's disapproval of DES as a "morning after" pill, about fifty percent of university health services and an unknown number of private physicians were

April (1995): page 25.

<sup>9</sup>Gorman, Christine. "The Estrogen Dilemma." *Time* 1 December (1997): page 77.

<sup>10</sup>"FDA Gives First Endorsement To "Morning After" Pill." *Nation's Health* March 27(3) (1997): page 4.

<sup>11</sup>Fenichell, Stephen & Charfoos, Lawrence S. *Daughter At Risk*. Garden City: Doubleday & Co., Inc, 1981, page 41.

<sup>6</sup>Mestel, Rosie. "A Safer Estrogen." *Health* November/December (1997): pages 73-76.

<sup>7</sup>"FDA Approves Low-Dose Estrogen for Osteoporosis." *Women's Health Weekly* 23 March (1998): page 14.

<sup>8</sup>Larkin, Marilynn. "Estrogen: Friend or Foe?" *FDA Consumer*

prescribing the "morning after" pill to some two million women without explicit disclosure of its experimental status.<sup>12</sup>

When it was finally established that this use of DES causes vaginal cancer, clear-cell adenocarcinoma to exposed daughters of women who used DES, possibly breast cancer to DES-using mothers, and prostate cancer to their sons, use of DES as a miscarriage prevention drug was banned from the market in the late 1970s. DES had also been prescribed to treat hormone deficiencies, menopause-related problems, advanced breast and prostate cancer, suppression of lactation, and as a postcoital contraceptive.<sup>13</sup> DES is still being used for some of these purposes, but has been discontinued for others because women experienced long-term complications such as cancer-related illness that need to be scrutinized.

Some doctors used DES as a "morning after" pill in the late 1950s because estrogen stops the egg from implanting in the uterus. Some users publicized that it was the safest way to prevent unwanted pregnancies. The typical dose prescribed by doctors was two 25mg tablets each day for five days. This contained about 500 times the amount of estrogen the body naturally produced.<sup>14</sup> The Planned Parenthood group surveyed two hundred women in Sacramento Valley to publicize the "morning after" pill usage. About thirty percent of the women knew the pill existed but they knew very little about the side effects. They just knew the drug was the way to avoid unintended pregnancy. Some users, particularly teenagers constantly overused the pills, thereby increasing the risk of negative long term consequences.

It was later revealed that some of the early tests indicating the safe use of DES as a "morning after" pill had incorporated false data. One university, "in the October 1971 *Journal of the American Medical Association*, [stated] that DES had proved one hundred percent effective as a postcoital contraceptive in 1000 women exposed to unprotected intercourse."<sup>15</sup> The National Institute of Health later discovered that some pregnancies had been excluded in the final report to make the drug appear to be a better postcoital contraceptive than it is. Only two years later, in 1973, the "FDA approved labeling for the first and only time for a "morning after" pill – a regimen of the estrogen diethylstilbestrol, or DES."<sup>16</sup> The public believed that DES used as a "morning after" pill would likely reduce the high numbers of abortions; therefore the members of the FDA approved the drug even though they had misgivings about its safety and effectiveness.

## JOURNALISM AS A SOURCE OF INFORMATION NECESSARY FOR SELF-GOVERNANCE

DES was generally believed to be the safest and most natural estrogen replacement back in the 1950s. The public did not know what to believe because they knew very little about the new drugs or their side effects. But journalists delivered an incomplete message about DES; continuing to assure people of the effectiveness of DES as a "morning after" pill even after it was suspected that there were serious side effects. This caused the public to push the FDA to approve the drug despite the dangers. This one-sided reporting may therefore indirectly endanger the health of many women. According to Deni Elliot's *Foundations for News Media Responsibility*, most people define journalists' special job as to tell the public the truth, get the story at all costs, be accurate about their sources, and speak for the downtrodden. Journalists do a good job of reporting the obvious news such as the drug examination done by the FDA and report when the drugs are placed on the markets. However, journalists do a very poor job of reporting complete stories. The information journalists deliver to the public is brief and broad; important details such as the serious side effects of DES are incompletely covered. *USA Today* submitted an article entitled "'Morning After' Pill Receives FDA Backing." The author reported that the "morning after" pill is supported by the FDA, is seventy-five percent effective, and is used when other methods fail. The author concluded that "it can cause side effects: nausea and vomiting."<sup>17</sup> The same message was delivered by *Women Health Weekly*, which stated "nausea and vomiting are common side effects" for the "morning after" pill.<sup>18</sup> Both discuss the safety of the "morning after" pill by stating that if the FDA approved it, it must be okay. A woman who takes the "morning after" pill will experience only nausea and possibly vomiting for now, but what will she experience ten years from the day she takes it? Does anyone mention that it causes abdominal pain, cramps, headaches, dizziness, and menstrual irregularities? In addition, the first dose may make her vomit repeatedly so that she can not consume the second dose or the following doses. Yet, *Public Health Reports* stated only that "risks, contraindications, and warnings are the same as for contraceptive drugs prescribed for daily use."<sup>19</sup> The *New York Times* described the side effects of the "morning after" pill as "considerably less unpleasant than [other] birth-control pills used for the same purpose." The author continued, "The failure rate is virtually nonexistent. And the method is simpler, because a woman needs only a single dose."<sup>20</sup>

<sup>12</sup>Weiss, Kay. "Vaginal Cancer: an Iatrogenic Disease?" *International Journal Health Service* 5.2 (1975): page 244.

<sup>13</sup>Myers, Robert. *DES: The Bitter Pill*. New York: Library of Congress, page 1.

<sup>14</sup>Ibid., page 184.

<sup>15</sup>Weiss, page 244.

<sup>16</sup>Hoffman, Jane. "The Morning After Pill." *New York Times Magazine* 10 January (1992): page 30.

<sup>17</sup>Painter, Kim. "'Morning After' Pill Receives FDA Backing." *USA Today* 25 February (1997): page 1A.

<sup>18</sup>Marble, Michelle. "'Morning After' Pills are Available, But Few Women Know." *Women's Health Weekly* 10 April (1995): page 9.

<sup>19</sup>"Pill Found Effective for Emergency 'Morning After' Use." *Public Health Reports* September/October (1996): page 389.

<sup>20</sup>Hoffman, page 14.

The author proclaims its one hundred percent effectiveness: no chance of failures. But according to the actual statistics, the "morning after" pill has a twenty-five percent chance of failure, and both these and the other seventy-five percent of the women may become seriously ill in the future as a result of taking the drug. Another article from *The Record, Hackensack, N.J.* had comparatively good coverage; it listed the side effects which "include nausea, vomiting, menstrual irregularities, breast tenderness, headaches, abdominal pain, and dizziness."<sup>21</sup> It did a great job reporting the short-term effects; however, no long-term effects are mentioned.

In order for many postcoital contraceptives to be effective and work correctly, a woman has to keep track of the doses; that is, if she misses one pill of the dose, she could risk becoming pregnant. If she changes her mind and does not complete the cycle of medications, then chances are that she will deliver a child who will later suffer from problems like reproductive abnormalities and certain types of cancer. It is likely that most women will find the "morning after" pill ineffective because the whole process takes five days, which is very long considering the potentially serious side effects when each dose is ingested. Moreover, about eighty percent of women who were treated (with the "morning after" pill) were not pregnant in the first place. A woman who is not pregnant is taking a completely unnecessary risk, a risk made worse by the high dose of estrogen. To quote Cynthia Laitman Orenberg's book entitled *DES: The Complete Story*:

Two physicians from the University of Washington reported in the March 6, 1980, issue of the *New England Journal of Medicine* that women who use estrogenic oral contraceptives run a nearly  $7\frac{1}{2}$  times greater risk of developing endometrial cancer than nonusers. Of some comfort is that the incidence of endometrial cancer is lower in women who use oral contraceptives containing mostly progesterone-like hormones (synthetic progesterones) rather than estrogen.<sup>22</sup>

Most prescription drugs which contain estrogen do so in small amounts. Over the course of the five day course of medication, the "morning after" pill delivers a large amount of estrogen. The monthly update of *Facts and Comparison* reported many problems regarding the use of estrogen in treating other diseases. The problems range from serious cancer to minor nausea. Drugs containing estrogen have been used to treat thromboembolic disease but result in a high risk of secondary diseases. The risks include thromboembolic and thrombotic vascular diseases, which

are also known as thrombophlebitis, pulmonary embolism, stroke and myocardial infarction. Retinal and mesenteric thrombolism and optic neuritis have been reported recently. Estrogen is used to treat breast and prostate cancer, but it can cause hypercalcemia. Side effects like breast cancer, estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding have been reported in many uses of estrogen.<sup>23</sup> High doses caused

edema (abnormal water retention) in the lining of the uterus ... [which] create an inhospitable environment for the implantation of a fertilized egg ... About one out of every 200 women who take DES as a postcoital contraceptive will become pregnant despite treatment.<sup>24</sup>

It seemed reasonable that drugs which contain lesser amounts of estrogen are better; this is why the FDA approved Estratab's 0.3mg pill for treatment of osteoporosis. It is unknown at this time if this lower dosage of estrogen will be safe.

#### CONCLUSION

The use of DES in the treatment of osteoporosis as well as other diseases may seem to be absolutely safe, but is far from risk-free. This is why the responsibility of journalists to tell the public the true story is so crucial; it affects women's decisions about their health. Although experts recognize the controversy in our society about drugs, to ensure that everyone understands the risks of treatments, journalists as well as the media need to report the whole and complete story, not just part of the news. They must not be biased or side with any one source. They need to report the differences to allow the public to make informed choices. The use of the "morning after" pill is dangerous because the long-term effects are not clear. Because of these long-term effects, journalists must not jump to conclusions in which they pressure the FDA to make wrong decisions. These decisions may influence the safety of the American public. Because the media has limited time and space to report news, it needs to deliver either the complete story or deliver nothing. The tragedy of daughters and sons who discovered they have cancer after their mothers ingested DES twenty years ago demands that these facts be told.

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<sup>21</sup>Lavelle, Louis. "FDA Approves New Jersey Firm's 'Morning After' Birth Control Pill." *The Record, Hackensack, N.J.* 4 September 1998: page 2.

<sup>22</sup>Orenberg, Cynthia Laitman. *DES: The Complete Story*. New York: St. Martin's Press, 1981, page 68.

<sup>23</sup>Ibid., page 69c.

<sup>24</sup>Ibid., page 69.

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DIANE-DINH KIM LUU is a freshman hoping to pursue a career in either optometry or pharmacy. She is currently completing her pre-professional program and minoring in Mathematics. This paper was written in Fall 1998 for H100, *Honors Freshman Colloquium*. Diane-Dinh chose this topic to learn more about the numerous aspects of the drug approval process.