PHARMACY EXAMINING BOARD
MINUTES
MADISON, WI
MARCH 11, 2003

PRESENT: Cynthia Benning, R.Ph.; Michael Bettiga, R.Ph.; John Bohlman, R.Ph; Georgina Forbes, Dan Luce, R.Ph; Charlotte Rasmussen, and Susan Sutter, R.Ph.

STAFF PRESENT: Thomas Ryan, Bureau Director; Deanna Zychowski, William Black, Legal Counsel; Pamela Meicher, Program Assistant; and Division of Enforcement staff for portions of the meeting.

GUESTS: Shelley Roebel, Purdue Pharmacy; Kurt Holm, RPH, Morton Pharmacy; Steve Morton, Morton Pharmacy; Janice Stat Paynter, Dean Pharmacy; Brian Mcthone, Walgreens; Dean Favors, UW Health; Jennifer Buechel, Lori Olson, Tara Knox, Wendy Vlietstra, Krista Pasek, Kathryn Grigg, Brenda Burke, Angela Ammon, Marie Beastrom, Amy Baron, Brianne Schmoller, Jessica Healy, Peter Smith, Rosalynn Flores, Jennifer Morzenti, Joe Stout, Nic Smith and Nick Sharrow all from the School of Pharmacy

CALL TO ORDER

Susan Sutter, Chair, called the meeting to order at 9:03 a.m. A quorum of seven members was present.

AGENDA

Additions/Changes to the Agenda:

Add under E – Senate Bill 21
Add under J – Correspondence re: Hospital pharmacy serving a nursing home with an Accu-Dose system
Add under J – Hospice and medication returns
Add under J – Variance on dispensing medications - Riverview Hospital Association
Add under J – Correspondence re: New federal rules regarding addiction treatment
Add under U – Case Closing 02 PHM 043
Add under V – NABP Correspondence
Add under V – Article "Illegal Business booming at Canadian drug outlets"

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, to approve the agenda as amended. Motion carried unanimously.

SECRETARY OF THE DEPARTMENT

Deputy Secretary Mary Schlaefer introduced herself to the Board. Deputy Secretary Schlaefer worked 13 years in the Department of Justice and most recently handled DRL cases. Ms. Schlaefer would like to work with DOE, the Boards and the department to improve the speed of disciplinary cases to ensure public health and safety. Ms. Schlaefer would also like to see

credential holder cases worked expeditiously. The Deputy Secretary will be working the day to day operations of the department and sees Board training and improving and or building on the support the department gives to the Board as top priorities

Patricia Hoeft, Division Administrator of Board Services worked most recently as the assistant director of St. Norbert College Alumni and Parent Relations. She is a former commissioner for the Oneida Gaming Commission. Over a ten year period, Ms. Hoeft served in various positions within the Oneida Tribe of Indians including legislative analyst and manager of the Legislative Reference Office.

Thomas Ryan, Bureau Director of Health Service professions has a Law degree and a Master's in health care administration. His regulatory works includes two years at Wisconsin Insurance Commission in the Health and Life section. He also worked in legal services in Medicaid and housing law.

Chair Susan Sutter had the Board members introduce themselves and give a brief history of their time on the Board.

MINUTES OF FEBRUARY 12, 2003

Corrections to the Minutes:

Page 1 – Correct spelling of HIPAA
Page 2 – Change the Wisconsin Pharmaceutical Association to the Pharmacy Society of Wisconsin.
Page 4 – Correct the spelling for HIPAA (two places.)
Page 4 – Change Chapter 146 to Chapter 146.82 (two places.)

MOTION: Charlotte Rasmussen moved, seconded by Dan Luce, to approve the minutes of February 12, 2003, as amended. Motion carried unanimously.

PRESENTATION OF PROPOSED STIPULATION

None.

SUMMARY REPORT ON PENDING COURT CASES, DISCIPLINARY CASES AND ADMINISTRATIVE RULES

A handout of pending cases was distributed and Pamela Haack advised the Board the report is up to date.

REVIEW AND APPROVAL OF PROPOSED ADMINISTRATIVE RULE RELATING TO CENTRAL FILL TO BE SENT TO LEGISLATURE

William Black, legal counsel, discussed all the changes made to the Administrative Rule relating to central fill. After the discussion, the Board decided that a second hearing should be held because of the changes made to the rule.

MOTION: Michael Bettiga moved, seconded by Dan Luce, to hold a second hearing on the proposed administrative rule relating to central fill. Motion carried unanimously.

MOTION: Cynthia Benning moved, seconded by John Bohlman, to approve the changes made to the administrative rule relating to central fill. Motion carried unanimously.

WISCONSIN STATUTES, CHAPTER 146 – CONSULTATION WITH AGENT OF PATIENT

William Black, legal counsel, gave the history of 1993 Assembly Bill 1061, covering various changes in the public records law and the law governing personal information practices.

LICENSING OF PHARMACISTS RESIDING IN CANADA

After a short discussion on visa status of applicants for Wisconsin licensure, the Board determined that visa status is not a factor when determining eligibility for licensure.

MOTION: Dan Luce moved, seconded by John Bohlman, that the Board agrees that a visa status is not an applicable factor in determining eligibility for licensure in Wisconsin. Motion carried unanimously.

REVIEW OF MANUFACTURER SELF-INSPECTION REPORT

William Black, legal counsel, discussed the Department of Regulation and Licensing Manufacturing Self-Inspection Report. The Board decided that they will use the FDA Inspection form as the inspection.

MOTION: John Bohlman moved, seconded by Georgina Forbes, that the Manufacturing Self-Inspection report form needs to be updated to reflect using the FDA Inspection form as the inspection. Motion carried unanimously.

SENATE BILL 21

The Board reviewed and discussed the handout covering Senate Bill 21. The Board decided to support some provisions and oppose other provisions in the bill without voting to support or oppose it in its entirety, as follows:

MOTION: Cynthia Benning moved, seconded by John Bohlman, that a pharmacist has the right to exercise professional judgment to refuse to fill a prescription, and the Board believes the pharmacist should not be the subject of adverse employment action because of it. However, the Board does not believe that SB21 is phrased appropriately to encompass that right because it is too narrowly drawn for just two specific instances. Adopted by voice vote, all voting aye. Motion carried unanimously.

VARIANCE REQUEST – MORTON PHARMACY – WISCONSIN RAPIDS

Morton Pharmacy would like a variance to delivery of a prescription by an agent of the pharmacist that can only be made to the patient's residence. Morton Pharmacy would like to allow patients to pick up prescriptions at work.

The Board requires more information before making a decision on this variance. In addition to the pharmacy policy, the Board would like to examine the phone log to ensure that patient consultation occurs. The Board would also require signature records that guarantee privacy. Delivery to patients must occur or the prescription must be returned. The Board would also like to ensure that the patient be informed that he or she may select where prescriptions are filled among market options.

VARIANCE REQUEST – NEIGHBORCARE PHARMACY – MENOMINEE – TECHNICIAN RATIO

The NeighhborCare Pharmacy is applying for a variance to extend the number of technicians that a pharmacist can supervise in his or her facility. The Board would like to see the pharmacy protocol on dispensing before it approves a variance.

VARIANCE REQUEST – RIVERVIEW HOSPITAL – WISCONSIN RAPIDS

Riverview Hospital is requesting a variance regarding the minimum equipment requirement. The Board requires more information on what the equipment provisions are and why certain equipment would not be used. The Board would like to know if the facility is open and whether it is compounding drugs.

REQUEST FOR APPROVAL OF TEMPORARY/REMODEL – WALGREEN'S #00649 – MILWAUKEE

MOTION: John Bohlman moved, seconded by Michael Bettiga, to approve the temporary/remodel of Walgreen #00649, in Milwaukee. Motion carried unanimously.

PRACTICE QUESTIONS

William Black, legal counsel, will draft a response to Donna James, RN, stating that he does not believe the pharmacies are releasing protected information to sales representatives. The doctor's name, the number of prescriptions, and the name of the drug are not considered protected health information. If Doctors object to the release of this information, they could address the issue of protecting their names. If the information received from the sales representative includes patient information, Ms. James should try to determine the source of that information, as it is protected.

William Black, legal counsel, will draft a response to Isaac Coggs Pharmacy, #7110-042, stating its pharmacists should use judgment as to where stock is stored and which area is used to counsel the patient.

William Black, legal counsel, will respond to the survey from Triplei.

William Black, legal counsel, will respond to the Marchland Pharmacies, Inc. questions re: Hospital Pharmacy serving a nursing home with an Accu-Dose system. Mr. Black believes it is acceptable institutional dispensing.

William Black, legal counsel, will respond to Douglas K. Foley, PharmD., regarding Hospice and medication returns, stating that if the location is DEA registered, they can be returned and also that the institution must be an inpatient facility as covered in the statutes.

William Black, legal counsel, will respond to Lori Breckheimer R.Ph., regarding her questions on dispensing. The Riverview Cancer Center must have a pharmacist, and the Board would like to invite Lori Breckheimer, R.Ph. to the next meeting to discuss both inpatient and outpatient requirements.

REPORT ON BUPRENORPHINE SEMINAR – DAN LUCE

Dan Luce, who attended a seminar with Arthur Thexton, Prosecuting Attorney for the Department of Regulation and Licensing, discussed the new federal rules regarding addiction treatment. A physician who has been disciplined or has a limited license will be eligible, under federal statute, to obtain an UIN (unique identifier number), and will be able to prescribe and dispense a Schedule III opioid for the purpose of treating addictive disease. A methadone clinic registration will not be needed because the only requirement is that the person hold a valid active license. The Medical Examining Board may wish to consider this in drafting future orders, and specifically restrict a licensee from maintaining or obtaining a UIN, in appropriate cases.

REPORT OF CONTROLLED SUBSTANCES BOARD – CYNTHIA BENNING

No new information is available at this time.

ADJOURN TO CLOSED SESSION

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to adjourn to closed session pursuant to Wisconsin State Statutes 19.85(1)(a)(b)(f) and (g), to review applications; deliberate on requests for stay of suspensions, proposed stipulations, case closings, review exam issues; and, consult with legal counsel. Roll Call Vote: Charlotte Rasmussen-yes; John Bohlman-yes; Michael Bettiga-yes; Dan Luce-yes; Cynthia Benning-yes; Susan Sutter-yes; Georgiana Forbes-yes. Motion carried unanimously.

Open session recessed at 1:25 p.m.

RECONVENE TO OPEN SESSION

MOTION: Dan Luce moved, seconded John Bohlman, to reconvene the meeting into Open Session at 2:40 p.m. Motion carried unanimously.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION, IF VOTING IS APPROPRIATE

REQUEST FOR MODIFICATION OF BOARD ORDER

MARK ANDERSON, RPH

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, to approve the modification of the Board Order in the matter of Mark Anderson, R.Ph,; to reduce his therapy from one session every four weeks to one session every eight weeks. Motion carried unanimously.

REQUESTS FOR THREE MONTH STAY OF SUSPENSION

CORY FORD, R.PH.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to grant a three month stay of suspension in the matter of Cory Ford, R.Ph. Motion carried unanimously.

GERALD JENNINGS, R.PH.

MOTION: Dan Luce moved, seconded by John Bohlman, to grant a three month stay of suspension in the matter of Gerald Jennings, R.Ph. Motion carried unanimously.

WILLIAM KARWOSKI, R.PH.

MOTION: Cynthia Benning moved, seconded by Georgina Forbes, to grant a three month stay of suspension in the matter of William Karwoski, R.Ph., and deny any modifications. Motion carried unanimously.

RALPH KOCH, R.PH.

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, to grant a three month stay of suspension in the matter of Ralph Koch, R.Ph. Motion carried unanimously.

PAUL NELSON, R.PH.

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to grant a three month stay of suspension in the matter of Paul Nelson, R.Ph. Motion carried unanimously.

DUANE OESTREICH, R.PH.

MOTION: Charlotte Rasmussen moved, seconded by Cynthia Benning, to grant a one month stay of suspension in the matter of Duane Oestreich, R.Ph., to request copies of the prescriptions he's taking from the start of the order, explain the positives in his screens, and request a report from his supervisor. Motion carried unanimously.

MICHAEL O'KRAY, R.PH.

MOTION: Cynthia Benning moved, seconded by John Bohlman, to grant a three month stay of suspension in the matter of Michael O'Kray, R.Ph., and deny any modifications. Motion carried unanimously.

ANDREW RICE, R.PH.

MOTION: John Bohlman moved, seconded by Dan Luce, to grant a three month stay of suspension in the matter of Andrew Rice, R.Ph. Michael Bettiga abstained. Motion carried.

THOMAS TRISCARI, R.PH.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to grant a three month stay of suspension in the matter of Thomas Triscari, R.Ph. Motion carried unanimously.

CHARLENE WILLIS, R.PH.

MOTION: Georgina Forbes moved, seconded by John Bohlman, to grant a three month stay of suspension in the matter of Charlene Willis, R.Ph., and deny any modifications. Motion carried unanimously. -

CASE CLOSINGS

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to close complaint **01 PHM 084,** for prosecutorial discretion (P2). Motion carried unanimously.

MOTION: Michael Bettiga moved, seconded by John Bohlman, to close complaint **02 PHM 023,** for prosecutorial discretion (P3). Dan Luce abstained. Motion carried.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to close complaint **02 PHM 043,** for prosecutorial discretion (P2). Motion carried unanimously.

EXAMINATION ISSUES - CASEY BROWN

Chairman Sutter will write a letter to Kris Hendrickson advising her that the cut off date and postmark date for application materials for the June 18, 2003 examination is May 19, 2003.

Chairman Sutter addressed the email from Mara Kieser, which stated that the Minnesota Board will not honor scores of the NABPLEX if the student takes the exam prior to graduation in Wisconsin. The Board will request NABP to survey other state boards to see what their stand is on this issue. The application may need to be changed explaining what the consequences would be in other states if they took the NABPLEX before graduation.

The Board met with Casey Brown to validate the exam results.

MOTION: Michael Bettiga moved, seconded by John Bohlman, to validate the exam results. Motion carried unanimously.

NAPB ANNUAL MEETING – MAY 3-7, 2003 – PHILADELPHIA

The Board noted that the NAPB annual meeting will be held in Philadelphia May 3-7, 2003.

OTHER BOARD BUSINESS

Four Board members will be attending the Wisconsin Pharmacy Leadership Summit on April 3, 2003.

ADJOURNMENT

MOTION: Michael Bettiga moved, seconded by John Bohlman, to adjourn the meeting. Motion carried unanimously.

Meeting adjourned at 3:00 p.m.

PRO-LIFE WISCONSIN

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P.O. Box 221
Brookfield, WI 53008-0221
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Matt Sande
Director of Legislative Affairs

www.prolifewisconsin.org
Your 100% pro-life voice.

September 27, 2003
2388 N. Lake Drive
Milwaukee, WI 53211

Senator Carol Roessler
Wisconsin State Capitol
Room 8 South
P.O. Box 7882
Madison, WI 53707-7882

Dear Senator Roessler and Senate Health, Children, Families, Aging and Long- Term Care Committee Members,

I write requesting that you return AB 67 back to its original form which protects pharmacists, nurses, physicians, and others from being fired for refusing to participate in "chemical" as well as surgical abortions.

I am a board certified OB/GYN physician. I am an associate clinical professor at the Medical College of Wisconsin and chairman of the OB/GYN department at St. Mary's Hospital in Milwaukee.

Among other duties, I teach medical students. I can tell you that by the time they are in their junior year, they know that many of the birth control devices and drugs labeled "contraceptive" are actually abortive at least some of the time. Birth control pills, according to standard medical textbooks and drug manufacturers' research, work by different mechanisms, including altering the uterine lining to interfere with implantation of the early embryo. Other methods, such as Norplant and IUD's also have both contraceptive and abortifacient mechanisms of action.

Clearly, even pro-abortion advocates recognize these facts. In the transcripts of the oral arguments of the case Webster v. Reproductive Health Services, there is an exchange between Supreme Court Justice Scalia and Frank Susman, the lawyer for the Missouri abortion clinic, demonstrating the point;

> "Justice Scalia: I don't see why a court can't separate abortion from birth control quite readily.
> Frank Susman: If I may suggest the reasons in response to your request, Justice Scalia. The most common forms of what we most generally in common parlance call contraception today, IUD's, low dose OCP's, act as abortifacients. They're correctly labeled as both."

If abortion is wrong because it takes an innocent life, then it is wrong whether it is done by surgery or by a chemical or other means. Those of us who object to abortion as a matter of conscience, and thus refuse to participate in it, ought not to lose our jobs whether we are pharmacists, nurses, techs, or physicians, and whether the instrument used in the abortion is a suction curette or a chemical.

Please restore AB 67 to its original form. Thank you.

Sincerely,

James Linn

James Linn, MD

September 17, 2003

Senator Carol Roessler

Wisconsin State Capitol

Room 8 South

P.O. Box 7882

Madison, WI 53707-7882

Dear Chairperson Roessler:

I would like to provide you with persuasive evidence in order to support truly comprehensive health care conscience clause legislation. If any health care conscience clause legislation is to move forward in the legislature, it must clearly protect pharmacists from employment discrimination if they conscientiously object to dispensing abortifacient "contraceptive" drugs and devices.

As you may know, there is good supporting evidence from primary medical literature that outlines the reality of postfertilization effects of oral contraceptives. Postfertilization effects are possible with breakthrough ovulation. Breakthrough ovulation occurs because of current low-dose estrogen (<35mcg) oral contraceptive pills. Please see the enclosed review article or retrieve the pdf document on-line at: http://archfami.ama-assn.org/cgi/reprint/9/2/126.pdf

I have a creed-based conscientious objection to participation in contraceptive articles. I am a Roman Catholic pharmacist and I have evidence to support my conscientious objection based on creed:

- "Defend the values that ennoble man. Do not be a party to attacks on human life or procreation," Holy Father tells Italian Pharmacists. *L'Osservatore Romano, N. 6-9 February 1994.*

- "All aggression against human life must be opposed; moral code must supersede laws of the marketplace." Pope tells Federation of Catholic Pharmacists. *L'Osservatore Romano, N. 46-12 November 1990.*

The following is a copy of an order I received last year from my licensing board for my refused participation in contraceptive articles:

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, that the attached Stipulation is accepted.

IT IS FURTHER ORDERED, that, Neil T. Noesen, R.Ph., is REPRIMANDED for his unprofessional conduct in this matter.

IT IS FURTHER ORDERED, that Respondent shall pay a FORFEITURE in the amount of $ 250.00, within 30 days of this order to the Department of Regulation and Licensing.

IT IS FURTHER ORDERED, that respondent shall pay COSTS in this matter in the amount of $ 300.00, within 30 days of this order to the Department of Regulation and Licensing.

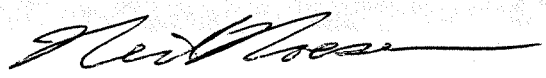
IT IS FURTHER ORDERED, that pursuant to §227.51(3), Wis. Stats., and ch. RL 6, Wis. Adm. Code, if the Board determines that there is probable cause to believe that respondent has violated any term of this Final Decision and Order, the Board may order that the license of respondent be summarily suspended pending investigation of the alleged violation.

Dated this _____, 2002.

I am contesting this order with the help of an attorney. This charge of "unprofessional conduct" is clearly an unjust discrimination on the part of the Wisconsin Department of Regulation and Licensing. This charge is unfair for Wisconsin pharmacists who have a conscientious objection to participation in contraceptive articles. We need your protection with your return of AB 67 back to its original form.

Kindly consider legislative reform of AB 67 which protects pharmacists and other health professionals (including doctors and nurses) from unfair prejudice and unjust discrimination.

Sincerely,



Neil Noesen, pharm D. (cand.)

Cc: Senator Tom Reynolds

September 7, 2003

Senator Carol Roessler
Wisconsin State Capitol
Room 8 South
P.O. Box 7882
Madison, WI 53707-7882

Dear Chairperson Roessler:

I am a registered pharmacist in southeastern Wisconsin and am writing regarding AB 67, which originally was designed to protect pharmacists such as myself as well as other health care professionals from participating in abortion and other life-ending procedures, including those abortions which occur at the chemical level. Because I believe that pharmacy is to be a totally life-saving profession, it goes against my conscience to dispense certain drugs which cause early abortion or intentional death of human life at any stage of development. Such drugs include many forms of contraception, including the birth control pill, contraceptive implants and injections, the pill used for "morning after" uses, and the IUD. Although birth control pills are supposed to and often do prevent ovulation, it is still possible for breakthrough ovulation, and thus, fertilization to occur. It is further possible that the hormones in the pill may alter the woman's uterine lining so that implantation of a newly formed embryo cannot occur and the embryo dies, which is a very early abortion. Some pills are more likely to "work" this way (that is, to prevent implantation) than others, especially when the pill is used as a "morning after" pill. However, such early abortions may occur with all types, including contraceptive implants and injections, and most definitely with the IUD.

Presently pharmacists have no protection against employment discrimination if they do not want to dispense drugs which have controversial mechanisms of action. Although there is an extremely high demand for pharmacists in our state, I have had to be very selective as to where I am willing to work because I cannot go against my conscience. Soon after I became licensed in this state, my husband and I moved to central Wisconsin where he had just accepted a job. Although pharmacy jobs in the retail sector were generally plentiful all around, I accepted a position at a newly created pharmacy in Stevens Point that served only nursing home patients. It was a 40 minute drive for me, but I knew I could work within my conscience at this pharmacy, as these patients were not prescribed any "contraceptives" which could cause chemical abortions. I actually would have preferred working in the retail sector but I didn't feel I had any protection if I requested to refrain from filling prescriptions that had abortifacient potential. I had interviewed for a store job in Wautoma prior to accepting the Stevens Point position and I did write a letter to my interviewer afterwards with my concern about dispensing such drugs, but he didn't seem to understand my position, telling me that pregnancy is defined as beginning at implantation. I didn't pursue this with him, however, because I soon found the nursing home position. Since then we have moved to southeastern Wisconsin and I am raising four young children. There are no nursing home positions fairly close to my home that I know of where I could work very part-time as I raise my children, although there are plenty of retail jobs close by.

Any health care conscious clause legislation that passes through Wisconsin's legislature needs to provide workplace protection for all health care providers, including pharmacists. If AB 67 is amended so that contraceptive articles are excluded from what health care providers would be protected from being required to provide, then the bill will basically hold no protection whatsoever for the pharmacists in this state who do not wish to participate in chemical abortion. This bill is not about taking away women's access to birth control. It is about respecting the rights of all health care providers who do not wish to participate in abortion, including chemical abortion. I ask you to seriously consider the rights of pharmacists and the preborn children they wish to protect and work to move AB 67 through in its original form.

Thank you very much.

Susan M. Grosskreuz, R.Ph.

Susan M. Grosskreuz, R.Ph.
6868 Northvue Ct.
West Bend, WI 53090

cc: Senator Tom Reynolds

Sept. 16, 2003

Senator Carol Roessler
Wisconsin State Capitol
Room 8 South
PO Box 7882
Madison, WI 53707-7882

Dear Chairperson Roessler:

I am a registered pharmacist in Wisconsin, and I am writing you in regards to AB 67, the conscience clause bill for health care workers. I understand that the original protection for pharmacists in exercising their conscience to not participate in abortions that are chemical in nature (i.e., oral contraceptives, morning-after pill, etc.) has been removed from this piece of legislation. I believe this is a step in the wrong direction. This will not only affect pharmacists like myself, but also nurses, physicians, and pharmacy technicians as well. Pharmacists are not the only ones that this issue applies to. What about the emergency room physician or nurse that doesn't feel right about dispensing the morning-after pill, but they are the "sexual assault" center for the area and their hospital mandates it? Also consider the situations when patients call the physician's office and would like refills on their oral contraceptive. The person that often authorizes these requests is the nurse, and they may not feel comfortable in this situation. And, what about the pharmacy technicians that work under pharmacists? They prepare the medication for dispensing. If they refuse to be involved, they could easily be terminated as well.

I feel that the legislation in its current form is discriminating against those of us that are just as competent and knowledgeable, and do not want to be involved in any level of abortion, be it chemical or surgical. The law has given people the "right" to participate in abortion, and I would like my right to not participate as a human being with a conscience; a medical professional that knows the truth of how these medications work and their dangers and doesn't try to hide that from the patients I serve. These medications can prevent implantation of a newly developing human embryo, and thus cause a chemical abortion (i.e. abortifacient).

I think we have to realize how many of our consciences have been desensitized to corporate America. I believe there are a lot more health professionals that would stand up and refuse to be involved, if they were rightly protected by the law, and would have no fear of losing their job, especially with the state of our economy today.

If I wanted to obtain a job in the retail sector, like Shopko, Walgreens, Osco, etc, I would be laughed out the door on the grounds of my conscientious objection. I am forced to work in a hospital where my conscience is silenced by the outside world.

I hope that you will restore AB 67 to its original form, and acknowledge the rights of every health care professional "to do no harm".

Sincerely,

Yvonne M. Rh

Yvonne Klubertanz, RPh
1030 W. Hawes Ave.
Appleton, WI 54914
WI license # 12883-040

Cc: Senator Tom Reynolds

SPECIAL ARTICLE

Postfertilization Effects of Oral Contraceptives and Their Relationship to Informed Consent

Walter L. Larimore, MD; Joseph B. Stanford, MD, MSPH

The primary mechanism of oral contraceptives is to inhibit ovulation, but this mechanism is not always operative. When breakthrough ovulation occurs, then secondary mechanisms operate to prevent clinically recognized pregnancy. These secondary mechanisms may occur either before or after fertilization. Postfertilization effects would be problematic for some patients, who may desire information about this possibility. This article evaluates the available evidence for the postfertilization effects of oral contraceptives and concludes that good evidence exists to support the hypothesis that the effectiveness of oral contraceptives depends to some degree on postfertilization effects. However, there are insufficient data to quantitate the relative contribution of postfertilization effects. Despite the lack of quantitative data, the principles of informed consent suggest that patients who may object to any postfertilization loss should be made aware of this information so that they can give fully informed consent for the use of oral contraceptives.

Arch Fam Med. 2000;9:126-133

Oral contraceptives (OCs) are among the most extensively studied and used medications in the world,[1] and are accessible without a prescription in some countries, although still virtually unavailable in others. In America, OCs have contributed to an increased acceptability of birth control,[2] although, for many patients, decisions about contraception still have moral, ethical, and religious implications.[3,4] For patients who believe that human life begins at fertilization (conception), a method of birth control that has the potential of interrupting development after fertilization (a postfertilization effect) may not be acceptable.[5,6] Postfertilization effects are operative for emergency (postcoital) contraception (when it is administered too late to prevent ovulation),[7,8] luteolytic agents (ie, RU-486),[9] and intrauterine devices,[5] and these methods therefore are unacceptable to some patients. Although postfertilization effects have been cited as a secondary mechanism of OCs,[10-12] the evidence for such effects has not been systematically reviewed. The purpose of this article was to review and grade the available evidence for postfertilization effects of OCs and discuss the implications for informed consent, based on the premise that patients to whom postfertilization effects are important have the right to make decisions based on the best available evidence.[13-15]

For Author's Comment see page 133

Our analysis of the evidence involved a review of the abstracts of all studies of OCs published since 1970 available on MEDLINE that discussed the commonly used OCs, including low-dose (<50 µg of estrogen) phasic combined oral contraceptives (COCs), low-dose monophasic COCs, and progestin-only OCs (progestin-only pills [POPs]). We also reviewed the patient handouts provided by OC manufacturers and the most recent editions of several medical textbooks and reference books.

Since there is variability in the definitions and use of terminology in reproductive medicine, we used the American

From the Department of Family Medicine, University of South Florida, Kissimmee (Dr Larimore), and Department of Family and Preventive Medicine, University of Utah, Salt Lake City (Dr Stanford).

Academy of Obstetrics and Gynecology Committee on Ethics' definitions for *fertilization*, *implantation*, *embryo*, and *preembryo*.[16] *Preembryo* is a general term that includes the human developmental stages that occur after fertilization but prior to the appearance of the primitive streak about 14 days after fertilization. From that point until the end of the eighth week after fertilization, the term *embryo* is used. Implantation is the process whereby the preembryo attaches to the endometrial lining of the uterus. This process begins 5 to 7 days after fertilization and may last several days. For this review, we defined *postfertilization effects* to include mechanisms of action that operate after fertilization to prevent a clinically recognized intrauterine pregnancy. We looked specifically for studies referencing any postfertilization effects of OCs. When many studies indicated similar findings, we listed the most recent or most methodologically sound references or other systematic or general reviews of particular subjects.

MECHANISMS OF OCs

The literature discusses several mechanisms for OCs. While the primary effect of OCs is the inhibition of ovulation via suppression of pituitary gonadotropin secretion (this mechanism is operative most of the time),[1,10,12] secondary effects are implicated at times of breakthrough ovulation to prevent clinically recognized pregnancy.[17,18] We classified these secondary effects as occurring either prefertilization or postfertilization. Secondary prefertilization effects may include alterations in cervical mucus that limit sperm penetration[2,17-20] and changes in the endometrium and fallopian tube that may impede normal sperm transport.[2,17,18,21]

Breakthrough ovulation rates vary by the form and the dose of the OC used.[2,10,12,18,22] With OCs, breakthrough ovulation is more likely with lower doses of estrogen and with imperfect rather than perfect use.[10,12,16,17,23-25] Perfect use of OCs implies taking them consistently and correctly (ie, in the correct order, on time, each and every day, and without other medications that might diminish the effectiveness of OCs). *Typical use* is described as the full range of usage patterns for OCs that actually occur in women.[1,11,12,18] While some smaller studies that evaluated small numbers of women for 6 or fewer cycles have reported breakthrough ovulation rates of near 0, studies that evaluated women for at least 6 cycles demonstrated ovulation rates ranging from 1.7%[25] to 28.6%[23] per cycle. For POPs, reported breakthrough ovulation rates range from 33%[26] to 65%.[20,27,28]

Obviously, breakthrough ovulation can result in unintended pregnancy[1,17,18]; however, the pregnancy rates with typical use vary widely and are often underestimated.[29] Unadjusted analyses of unintended pregnancies while using COCs report rates of 0.1 to 1.0 per 100 woman-years of use in perfect use and 3 per 100 woman-years in the first year of typical use.[1,10,12,17,18,20] Most of these data do not account for elective abortions. One national analysis that accounted for the underreporting of elective abortions estimated that the unintended pregnancy rates during the first year of OC use were 4% for "good compliers," 8% for "poor compliers," and up to 29% for some users.[29] Rates of pregnancy are higher with POPs than with COCs.[1,17,18] Unadjusted analyses of pregnancies while taking POPs reported rates of 0.5 to 1.0 per 100 woman-years of perfect use and 3 to 7 per 100 woman-years in the first year of typical use.[1,10,12,17,18,20] However, these rates have not been adjusted for elective abortions and are almost certainly underestimated.[29] Progestin-only pills are reported to have potent effects on both cervical mucus and the endometrium.[19-21,30,31] While this has led to speculation that "the principal mode of action is . . . to make the cervical mucus hostile to the transport of the sperm,"[17] animal model data[32] and data on ectopic pregnancy rates (reviewed below) suggest that postfertilization effects also play a role.

In theory, postfertilization effects of OCs could involve any 1 or more of the following 3 mechanisms of action: (1) A postfertilization preimplantation effect would consist of a slower transport of the preembryo through the fallopian tube, preventing the preembryo from implanting in the uterus; this could result either in the unrecognized loss of the preembryo or in an ectopic (tubal) pregnancy if the preembryo had slower tubal transport and ended up implanting in the fallopian tube. (2) A peri-implantation effect would be the alteration of the endometrium, such that a preembryo that reached the uterus was unable to successfully implant into the endometrial lining of the uterus. (3) A postimplantation effect could result from alteration of the endometrium not sufficient to prevent implantation but unfavorable for maintenance of the pregnancy; a preembryo or embryo already implanted in the endometrial lining of the uterus would be unable to maintain itself long enough to result in a clinically recognized pregnancy.

EVIDENCE FOR POSTFERTILIZATION EFFECTS

Direct evidence of postfertilization preimplantation and peri-implantation effects would require methods that directly measured the rate of fertilization and the loss of the preembryo in women taking OCs. Transcervical tubal washings have been used in women using intrauterine devices to quantify the rate of ova fertilization[33] and could theoretically be done for women taking OCs. However, there is no proven method to measure the loss of the preembryo prior to implantation, even though a number of possible methods have been investigated that involve maternal hormones that may be produced or altered after fertilization.[34-36] Probably the most promising method is the isolation of "early pregnancy factor."[37-39]

Direct evidence of a postimplantation effect on the preembryo or embryo prior to clinically recognized pregnancy would require measurement with ultrasensitive assays for β–human chorionic gonadotropin (β-HCG) or other pregnancy-related hormones.[40] Although ultrasensitive assays for β-HCG have been done with normally fertile women not using OCs,[41-44] as well as with women using nonhormonal methods of contraception,[45] we could find no such

Quality of Evidence*		
Excellent	I	Evidence obtained from at least one properly randomized controlled trial.
Very good	II.1	Evidence obtained from well-designed controlled trials without randomization.
Good to very good	II.2	Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group.
Good	II.3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
Poor to good	III	Opinion of respected authorities based on clinical experience, descriptive studies and case reports, or reports of expert committees.

**Adapted from Berg.*[46]

studies in women using OCs. Despite the lack of these data, at least 3 lines of evidence have been suggested to support the hypothesis that 1 or more postfertilization effects are operative in at least some women taking OCs. Using a standard quality of evidence table[46] (**Table**), we graded the available evidence.

Endometrial Changes That May Affect Endometrial Receptivity

Oral contraceptives directly affect the endometrium.[1,10,12,20,21] These effects have been presumed to render the endometrium relatively inhospitable to implantation or to the maintenance of the preembryo or embryo prior to clinically recognized pregnancy by producing a predecidual or decidualized endometrial bed with diminished thickness and with widely spaced, exhausted, and atrophied glands; by altering the cellular structure of the endometrium, leading to the production of areas of edema alternating with areas of dense cellularity[18,20,21]; and by altering the biochemical and protein composition of the endometrium.[47]

Although these changes are consistently seen in women taking OCs, there is currently no direct evidence to link these changes to preembryo or embryo loss in women taking OCs. However, this hypothesized postfertilization effect seems to be so well accepted that in many medical articles and textbooks it has been explicitly listed as the third mechanism of OCs (after suppressing ovulation and prefertilization effects).[1,10,17,18] For example, the Food and Drug Administration–approved product information for OCs in the *Physicians' Desk Reference* states,

> Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus, which increase the difficulty of sperm entry into the uterus, and changes in the endometrium, which reduce the likelihood of implantation.[11]

An independent clinical pharmaceutical reference also contains this assertion.[12] We considered this level III (poor to good) evidence (Table).

To assess the clinical significance of an altered endometrium, it was helpful to examine data that compared endometrial thickness with the receptivity of the endometrium to preembryos during in vitro fertilization procedures. Magnetic resonance imaging scans of the uteri of women reveal that the OC users have endometrial linings that are consistently thinner than the endometrial linings of nonusers,[48-50] up to 58% thinner.[51] Of the first 4 ultrasound studies published, the first did not find a relationship between endometrial thickness and in vitro fertilization implantation rates[52]; however, subsequent studies noted a trend,[53,54] and one demonstrated that a decreased thickness of the endometrium decreased the likelihood of implantation.[55] Larger, more recent, and more technically sophisticated studies[56-65] all concluded that endometrial thickness is related to the functional receptivity of the endometrium. Furthermore, when the endometrial lining becomes too thin, then implantation does not occur.[56-58,64,65] The minimal endometrial thickness required to maintain a pregnancy in patients undergoing in vitro fertilization has been reported, ranging from 5 mm[55] to 9 mm[65] to 13 mm,[53] whereas the average endometrial thickness in women taking OCs is 1.1 mm.[50] These data would seem to lend credence to the Food and Drug Administration–approved statements that " . . . changes in the endometrium . . . reduce the likelihood of implantation."[11] We considered this level II.2 (good to very good) evidence (Table).

Integrin Changes Affecting Fallopial Tube and Endometrial Receptivity for Implantation

Integrins are a family of cell adhesion molecules that are accepted as markers of uterine receptivity for implantation.[66,67] Temporal and spatial expression of these endometrial peptides is believed to contribute to the establishment and maintenance of a cyclical endometrial receptivity. Three cycle-dependent integrins ($\alpha 1\beta 1$, $\alpha 4\beta 1$, $\alpha V\beta 3$) have been shown to be " . . . coexpressed apparently only for a brief interval of the cycle that corresponds with the putative window of maximal uterine receptivity" and " . . . have emerged as reliable markers of normal fertility."[68] Of these 3, the $\alpha V\beta 3$ integrin seems "to be an excellent marker to study the molecular events leading to the establishment of uterine receptivity and successful implantation."[68,69] These 3 integrins are conspicuously absent in the endometrium of most patients with luteal phase deficiency, endometriosis, and unexplained infertility.[68]

In addition, integrin expression is significantly changed by OCs. Integrins have been compared using endometrial biopsy specimens from normally cycling women and women taking OCs. In most OC users, the normal patterns of expression of the integrins are grossly altered, leading Somkuti et al[68] to conclude that the OC-induced integrin changes observed in the endometrium have functional significance and provide evidence that reduced endometrial receptivity does indeed contribute to the contracep-

tive efficacy of OCs. They hypothesized that the sex steroids in OCs alter the expression of these integrins through cytokines and therefore predispose to failure of implantation or loss of the preembryo or embryo after implantation. We considered this level II.3 (good) evidence (Table).

Integrins have also been identified in the fallopian tube.[69] Of interest, the αV subunit is expressed in the fallopian tube epithelium throughout the cycle, but the β3 subunit is only upregulated during the period of endometrial receptivity. Therefore, it has now been postulated that the normal tubal epithelium also has an implantation window that " . . . affords the opportunity for trophoblast attachment should a 5-7 day preembryo be unduly retained in the tube."[69] As discussed earlier, one of the postulated actions of the OCs is a slowing of tubal peristalsis (via smooth muscle relaxation)[70]; therefore, a reduction in tubal peristalsis that is associated with an upregulation of the αVβ3 integrin in the epithelium of the fallopian tube could theoretically lead to an increased risk of ectopic pregnancies in women taking OCs.

If breakthrough ovulation occurs while using the COC, then to some extent ovarian and blastocyst steroidogenesis could theoretically "turn on" the endometrium, causing it to normalize prior to implantation in the ovulatory cycle. However, after discontinuing use of COCs, it usually takes several cycles for a woman's menstrual flow to approach the volume of women who have not taken hormonal contraception,[71] suggesting that the endometrium is slow to recover from its COC-induced atrophy. Furthermore, in women who have ovulated secondary to missing 2 low-dose COCs, the endometrium in the luteal phase of the ovulatory cycle has been found to be nonsecretory.[23]

Increased Extrauterine Pregnancy to Intrauterine Pregnancy Ratio

If the action(s) of OCs on the fallopian tube and endometrium were such as to have no postfertilization effects, then the reduction in the rate of intrauterine pregnancies in women taking OCs should be proportional to the reduction in the rate of extrauterine pregnancies in women taking OCs. If the effect of OCs is to increase the extrauterine-to-intrauterine pregnancy ratio, this would indicate that one or more postfertilization effects are operating. All published data that we could review indicated that the ratio of extrauterine-to-intrauterine pregnancies is increased for women taking OCs and exceeds that expected among control groups of pregnant women not currently using OCs. These case-controlled series come from 33 centers in 17 countries and include more than 2800 cases and controls.[72-77] The odds ratios in these studies ranged from 1.7 (95% confidence interval [CI], 1.1-2.5)[72] to 1.8 (95% CI, 0.9-3.4)[73] to 4.3 (95% CI, 1.5-12.6)[74] to 4.5 (95% CI, 2.1-9.6)[75] to 13.9 (95% CI, 1.8-108.3).[76] The letter by Job-Spira et al[74] seems to represent the same data set of 279 cases and controls as the study by Coste et al.[76] The meta-analysis by Mol et al[73] includes 2 of the publications,[72,75] but one of these may include women taking POPs.[72] Therefore, of the 5 publications, only 2 allow review of the association of COCs with ectopic pregnancy.[75,76] These 2 studies from 7 maternity hospitals in Paris, France, and 3 in Sweden involved 484 women with ectopic pregnancies and 289 pregnant controls and suggest that at least some protection against intrauterine pregnancy is provided via postfertilization preimplantation effects. We recognize that studies that have used nonpregnant controls have not shown a risk of increased ectopic pregnancy for users of COCs. In our review, we restricted our analysis to studies using pregnant controls, because we concur with researchers[73,76] in this field that " . . . when considering the situation where a woman became pregnant during contraceptive use, one should focus on pregnant controls."[73] Therefore, COC use seems to be associated with an increased risk of ectopic implantation or unrecognized loss of preembryos. We considered this level II.2 (good to very good) evidence (Table).

Ectopic pregnancy is a particular form of postfertilization loss that involves substantial risks to the woman, and thus the absolute risk of ectopic pregnancy for women taking OCs will be of interest to clinicians and patients. Converting a relative risk of ectopic pregnancy to an absolute risk has many inherent difficulties that have been reviewed elsewhere.[78] Nevertheless, adapting the method suggested by Franks et al[78] would allow one to predict that the ectopic pregnancy rate for women taking OCs would be the product of 3 factors: (1) the overall pregnancy rate per 1000 woman-years among those taking OCs, (2) the proportion of extrauterine pregnancies compared with all pregnancies for a comparable control population not taking OCs, and (3) the relative risk for ectopic pregnancy in women taking OCs compared with the control population, which may be estimated by the odds ratio from case-control studies. For factor 1, Potter[29] suggests 40 for good compliers and 80 for poor compliers. For factor 2, the proportion of ectopic pregnancies in the 1990s is estimated to range from 1 in every 56[79] to 64[80,81] pregnancies (0.0156 to 0.0179). A reasonable range for factor 3 would be 1.1 to 13.9, based on the studies discussed above. This model would predict an absolute risk ranging from 0.7 ($40 \times 0.0156 \times 1.1$) to 19.9 ($80 \times 0.0179 \times 13.9$) ectopic pregnancies per 1000 woman-years. We could only find one study, from Zimbabwe, which reported an absolute risk of ectopic pregnancy in women taking OCs of 0.5[82] per 1000 woman-years.

The risk of ectopic pregnancy is higher with POPs, and ectopic pregnancy has been discussed at length by a number of investigators as a clinically significant potential complication of POPs.[82-84] The odds ratio of an extrauterine pregnancy for a woman taking a POP (compared with pregnant controls) was reported in only one study and was 79.1 (95% CI, 8.5-735.1).[74] Assuming an overall clinical pregnancy rate of 30 to 70 per 1000 woman-years, this equates to a predicted absolute risk of 4 to 99 ectopic pregnancies per 1000 woman-years ([30 or

70] × [0.0156 or 0.0179] × [8.5 or 79.1]) in women taking POPs. This is reasonably concordant with absolute rates of ectopic pregnancy in women taking POPs, which have been reported to range from about 3[82,83,85] to about 20[84,86] per 1000 woman-years.

Data from case-controlled series demonstrate that women with clinically recognized pregnancy are no more or less likely to miscarry based on whether they were taking an OC after their pregnancy was clinically recognized.[87-90] However, the epidemiology, biology, and recognized risk factors of clinically recognized embryo or fetal loss (spontaneous abortion after clinically recognized pregnancy) do not seem to apply to early (unrecognized) preembryo or embryo loss, as the available evidence suggests that the mechanisms of early establishment and maintenance of pregnancy and later maintenance of pregnancy are qualitatively and substantially different.[90]

COMMENT

We found the evidence supporting postfertilization effects for OCs in the prevention of clinically recognized pregnancy to range from poor (level III) to very good (level II.2). Specifically, evidence based on alterations in endometrial biochemistry and histology (level III), evidence based on endometrial thickness and endometrial receptivity from research studying in vitro fertilization (level II.2), and evidence based on endometrial integrins (level II.3) all support the possibility of peri-implantation or postimplantation effects. Furthermore, evidence based on ectopic-to-intrauterine risk ratios from multiple case-control studies (level II.2) supports the possibility of postfertilization preimplantation, peri-implantation, or postimplantation effects. However, we could identify few data that would assist in quantifying these postfertilization effects. It seems likely that for perfect use of COCs, postfertilization mechanisms would be likely to have a small but not negligible role. For POPs, COCs with lower doses of estrogen, and imperfect use of any OCs, postfertilization effects are likely to have an increased role. In any case, the medical literature does not support the hypothesis that postfertilization effects of OCs do not exist.

Despite the evidence, which suggests that postfertilization effects for OCs are operational at least some of the time, and the fact that a postfertilization mechanism for OCs is described in the *Physicians' Desk Reference*,[11] in *Drug Facts and Comparisons*,[12] and in most standard gynecologic, family practice, nursing, and public health textbooks, we anecdotally find that few physicians or patients are aware of this possibility. Therefore, we believe that the potential for postfertilization effects is probably not routinely presented to patients as part of their informed consent to use an OC. Furthermore, it is of concern to us that only one of the many OC patient information handouts we and others[5] have reviewed, including those produced by the OC manufacturers, mentions the possible postfertilization mechanism, despite the fact that this information is nearly always included in the professional labeling of these same OCs.

Since there is evidence to support the existence of postfertilization effects and because it is impossible to know in advance which patients would find the potential for this effect objectionable, we believe that the lack of information regarding postfertilization effects in patient information materials about OCs represents a potential failure to provide complete informed consent. Furthermore, if this mechanism of an OC violates the moral requirements of a woman, then failure to disclose this information seriously jeopardizes her autonomy. If information about the mechanism of an OC is deliberately withheld or misstated, then an unethical deception occurs. Failure to disclose information that might lead a patient to choose a different method of treatment is generally considered to be unethical.[12,13] Therefore, it seems clear to us that failure to inform patients of a possible postfertilization mechanism of an OC is a failure to provide informed consent.

PROVIDING INFORMED CONSENT

Many reproductive scientists have defined pregnancy as occurring at the point of or at some point after implantation.[16,91,92] However, this definition does not change the fact that some patients, for personal, scientific, moral, or religious reasons, identify the start of human life at fertilization. For such patients, a form of contraception that allows fertilization and then causes loss of the preembryo or embryo may be unacceptable. Regardless of the personal beliefs of the physician or provider about the mechanism of OCs, it is important that patients have information relevant to their own beliefs and value systems.

However, the objective presentation of the potential for postfertilization effects of OCs may be complex; there are a variety of potential interpretations of the postfertilization effects depending on which aspect is emphasized: (1) One could state that OCs may significantly reduce the absolute risk per woman-year of any possible postfertilization loss in the same way that they reduce the absolute clinical pregnancy rate.[78] For some women or medical personnel who believe that human life begins at fertilization, this view might render OCs, even with postfertilization loss, morally acceptable. (2) One could emphasize that once fertilization has occurred, OCs may cause at least an occasional postfertilization loss, regardless of the rate of fertilization. For some women or medical personnel who believe that human life begins at fertilization, the view that any postfertilization loss could be attributed to the effects of OCs and therefore could be considered induced rather than natural may render OCs morally unacceptable to use, even if the absolute frequency of such an event is very low.

Medical colleagues have suggested to us that postfertilization loss attributed to OCs would not need to be included in informed consent until it is either definitely proven to exist or proven to be a common event. However, rare but important events are an essential part of other informed consent discussions in medi-

cine, primarily when the rare possibility would be judged by the patient to be important. For example, anesthesia-related deaths are extremely rare for elective surgery (<1:25 000 cases); nevertheless, it is considered appropriate and legally necessary to discuss this rare possibility with patients before such surgery because the possibility of death is so important. Therefore, for women to whom the induced loss of a preembryo or embryo is important, failure to discuss this possibility, even if the possibility is judged to be remote, would be a failure of informed consent. Others feel that an overemphasis of possible postfertilization effects might make women choose a less-effective method of contraception and therefore increase the incidence of unplanned pregnancy. Both of these views fail to acknowledge the value of a woman's autonomy in making decisions based on informed consent. During informed consent discussions, overemphasis of any single possible risk may not result in appropriate informed consent; however, neither does choosing to not mention the possible risk result in adequate informed consent. Therefore, discussion of this potential risk should occur and should be kept within the perspective of the available medical evidence.

One possible approach to this complex issue might be to inquire of the patient whether she desires this information. The physician or provider might say, for example: "Most of the time, the pill acts by preventing an egg from forming. This prevents pregnancy. However, women on the pill can still sometimes get pregnant. Some doctors think that the pill may cause the loss of some of these pregnancies very early in the pregnancy, before you would even know you were pregnant. Would knowing more about this possibility be important to you in your decision about whether to use the pill?"

If the answer is yes, further explanation of the issues would be indicated and should occur in terms that are as understandable as possible. Proper informed consent requires patient and physician comprehension of information, the disclosure of this information, and the sharing of interpretations.[14,15] If any mechanism of any OC violates the morals of any particular woman, the failure of the physician or care provider to disclose this information would effectively eliminate the likelihood that the woman's consent was truly informed[13,14,93] and would seriously jeopardize her autonomy.[13]

Furthermore, there is a potential for negative psychological impact on women who believe human life begins at fertilization, who have not been given informed consent about OCs, and who later learn of the potential for postfertilization effects of OCs.[94] The responses to this could include disappointment, anger, guilt, sadness, anger, rage, depression, or a sense of having been violated by the provider.[5] Further research is necessary to identify the exact frequency of postfertilization effects of OCs.

CONCLUSIONS

The available evidence supports the hypothesis that when ovulation and fertilization occur in women taking OCs, postfertilization effects are operative on occasion to prevent clinically recognized pregnancy. Physicians should understand and respect the beliefs of patients who consider human life to be present and valuable from the moment of fertilization. Since it would be difficult to predict which patients might object to being given an OC if they were aware of possible postfertilization effects, mentioning the potential for postfertilization effects of OCs to all patients and providing detailed information about the evidence to those who request it is necessary for adequate informed consent.

Accepted for publication March 18, 1999.

We thank John R. Hartman, MD, Chris Kahlenborn, MD, G. Gayle Stephens, MD, William Toffler, MD, and Randy Alcorn, MS, for their help with conceptual development of this article and for identifying important references.

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Author's Comment

I have prescribed "the Pill" since 1978. My wife and I used the Pill for years, having no moral concerns about it. Then, in 1995 my friend and practice partner John Hartman, MD, showed me a patient information brochure—given to him by a friend—that claimed the Pill had a postfertilization effect causing " . . . the unrecognized loss of preborn children." John asked me if I had ever heard of such a thing. I had not. I did read the brochure and its claims seemed to be outlandish, excessive, and inaccurate. So, I decided to begin a literature search to disprove these claims to my partner, myself, and any patients who might ask about it. The more research I did, the more concerned I became about my findings. I called researchers around the country and interviewed them. During this process I met Joe Stanford, MD. Joe volunteered to assist in the research that ultimately became this systematic review. We were concerned enough about our findings and about the fact that so many of our colleagues and patients seemed to share our ignorance about this potential effect that we presented the preliminary results of our research at a number of research forums, just to see if we were off base. Most of the reviewers suggested that, although this evidence was new to them (as it was to us), it seemed accurate and not off target. Furthermore, several said that they thought it would change the way family physicians informed their patients about the Pill and its potential effects.

The most difficult part of this research was deciding how to apply it to my practice. I discussed it with my partners, my patients, ethicists I know and respect, and pastors in my community. I studied the ethical principle of double effect and discussed the issue with religious physicians of several faiths. Finally, after many months of debate and prayer, I decided in 1998 to no longer prescribe the Pill. As a family physician, my career has been committed to family care from conception to death. Since the evidence indicated to me that the Pill could have a postfertilization effect, I felt I could no longer, in good conscience, prescribe it—especially since viable alternatives are available. The support and encouragement that my partners, staff, and patients have given me has been unexpectedly affirming. It seems that my patients have appreciated the information I have given them. Many have been surprised or even shocked (as I was) to learn about this potential effect. Many of my patients have chosen to continue taking the Pill, and we have physicians in our practice and community who will prescribe it for them. Patients who take the Pill tell me that they are much more careful with their compliance. Others have chosen other birth control options—especially one of the modern methods of natural family planning. So, this is research that has changed my soul and my practice. It has been an extraordinarily difficult issue with which I have had to wrestle. I suspect it will be so for many who thoughtfully read and consider the evidence contained in this review.

Walter L. Larimore, MD
Kissimmee, Fla

WISCONSIN LEGISLATIVE COUNCIL

Terry C. Anderson, Director
Laura D. Rose, Deputy Director

TO: REPRESENTATIVE STEPHEN NASS

FROM: Robert J. Conlin, Senior Staff Attorney

RE: 2003 Assembly Bill 67 and Assembly Substitute Amendment 1, Relating to a "Conscience Clause" for Health Care Providers

DATE: April 21, 2003 (Revised April 22, 2003)

The first part of this memorandum provides a brief description of the substantive differences between 2003 Assembly Bill 67 and Assembly Substitute Amendment 1 (hereinafter, ASA 1), a proposed substitute amendment to the bill. The second part of this memorandum briefly describes current law and offers a more extensive description of ASA 1.

As you know, the bill provides certain employment-related and other protections for health care providers and other individuals who refuse to participate in certain procedures. The bill had a public hearing before the Assembly Labor Committee on March 5, 2003.

The substantive provisions of Assembly Bill 67 were described in the bill's Legislative Reference Bureau analysis and in a memorandum from me to Representative Nass dated February 27, 2003 and made public on March 3, 2003.

DIFFERENCES BETWEEN ASSEMBLY BILL 67 AND ASA 1

In general, the bill and ASA 1 are nearly identical. However, ASA 1 makes several changes to the bill which are discussed below.

Separate Cause of Action

As you know, Assembly Bill 67 not only created a clear cause of action under the Wisconsin Fair Employment Act for employees and prospective employees discriminated against for their refusal to participate in certain activities, it also created a separate cause of action. Under the bill's separate cause of action, a person who is adversely affected by, or who reasonably may be expected to be adversely affected by, conduct that violates certain provisions of the bill (e.g., adverse employment action based on a refusal to participate in certain activities) may bring a civil action for injunctive relief, including

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reinstatement, or damages, including damages for emotional or psychological distress, or both. Generally, such actions must be commenced within six years after the cause of action accrues.

ASA 1 provides that this separate cause of action does not apply to claims that are subject to the Wisconsin Fair Employment Act. In addition, ASA 1 deletes the ability of a person "who reasonably may be expected to be adversely affected" by conduct that violates certain provisions to file a separate cause of action. ASA 1 also modifies the remedy available to a person filing a separate cause of action. Under ASA 1, a successful claimant may obtain equitable relief, including reinstatement, or damages, or both. For purposes of ASA 1, damages ***does not*** include "noneconomic damages" as described in current law.[1] Finally, ASA 1 requires that the separate cause of action be commenced within one year after the cause of action accrues.

"Participate In"

Under the bill, the term "participate in" is defined to mean "to perform, assist in, recommend, counsel in favor of, make referrals for, prescribe, dispense, or administer drugs for, or otherwise promote, encourage, or aid."

ASA 1 modifies the definition of "participate in" to mean "to perform; practice; engage in; assist in; recommend; counsel in favor of; make referrals for; prescribe, dispense, or administer drugs or devices, other than contraceptive articles, as defined in s. 450.155 (1) (a), for or otherwise promote, encourage, or aid." For purposes of ASA 1, "contraceptive article" means any drug, medicine, mixture, preparation, instrument, article, or device of any nature used or intended or represented to be used to prevent a pregnancy. [See s. 450.155 (1) (a), Stats.]

In addition, ASA 1 uses the phrase "participate in" consistently throughout the draft.

Licensed Practical Nurses

The bill provides certain protections for a person licensed as a registered nurse based upon his or her refusal to participate in various activities.

ASA 1 expands the protections to apply to a person licensed as a practical nurse.

Revision of Objectionable Activities

Generally, the bill provides protections for health care professionals who refuse to participate in six specified activities. One of those activities included participating in an experiment or medical procedure involving: (1) the destruction of a human embryo; or (2) a human embryo or unborn child, at any stage of development, in which the experiment or procedure is not related to the beneficial treatment of the human embryo or unborn child.

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[1] Current law defines "noneconomic damages" to mean "moneys intended to compensate for pain and suffering; humiliation; embarrassment; worry; mental distress; noneconomic effects of disability including loss of enjoyment of the normal activities, benefits and pleasures of life and loss of mental or physical health, well-being or bodily functions; loss of consortium, society and companionship; or loss of love and affection." [s. 893.55 (4) (a), Stats.]

ASA 1 deletes the above-described procedure and instead substitutes the following three procedures:

1. An experiment or medical procedure that destroys an in vitro human embryo or uses cells or tissue derived from the destruction of an in vitro human embryo.

2. An experiment or medical procedure on an in vitro human embryo that is not related to the beneficial treatment of the in vitro human embryo.

3. An experiment or medical procedure on a developing child in a natural or artificial womb, at any stage of development, that is not related to the beneficial treatment of the developing child.

ASA 1 defines an "in vitro human embryo" as a "human embryo, whether cryopreserved or not, living outside of a woman's body."[2]

Technical Changes

ASA 1 also makes certain technical changes so that the amendments made to ch. 448, Stats., are consistent with the changes made in chs. 441 and 450, Stats.

CURRENT LAW AND ASA 1 TO ASSEMBLY BILL 67

The remainder of this memorandum will briefly describe current law and the provisions of ASA 1 to Assembly Bill 67.

Current Law

WFEA

Wisconsin's Fair Employment Act (WFEA) generally prohibits discrimination in employment and licensure based on, among other things, a person's creed. For purposes of the WFEA, "creed" is defined as a system of religious beliefs, including moral or ethical beliefs about right and wrong, that are sincerely held with the strength of traditional religious views. [s. 111.32 (3m), Stats.] Under the WFEA, employment discrimination because of creed specifically includes refusing to reasonably accommodate an employee's or prospective employee's religious observance or practice unless the employer can demonstrate that the accommodation would pose an undue hardship on the employer's program, enterprise, or business.

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[2] Both the bill and ASA 1 define the term "human embryo" to mean "a human organism that is derived from fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells." Under both the bill and ASA 1, a human embryo includes a zygote but does not include a human organism at or beyond the stage of development at which the major body structures are present.

Refusal to Perform Certain Procedures

Under current law, no hospital may be required to admit a patient or to allow the use of its facilities for the purpose of performing a sterilization procedure or removing a human embryo or fetus. A physician or any other person who is a member of or associated with the staff of a hospital, or an employee of the hospital in which such a procedure has been authorized, may not be required to participate in such procedure if his or her objection is stated in writing and is based on moral or religious grounds. Such a refusal to participate in a procedure may not form the basis of any claim for damages on account of such refusal or for any disciplinary or recriminatory action against the person. [s. 253.09 (1), Stats.]

In addition, no hospital or employee of any hospital may be held liable for any civil damage resulting from a refusal to perform sterilization procedures or to remove a human embryo or fetus from a person, if such refusal is based on religious or moral precepts. [s. 253.09 (2), Stats.] The law also prohibits any hospital, school, or employer from discriminating against any person with regard to admission, hiring or firing, tenure, term, condition or privilege of employment, or student or staff status on the ground the person refuses to recommend, aid, or perform procedures for sterilization or the removal of a human embryo or fetus, if the refusal is based on religious or moral precepts. [s. 253.09 (3), Stats.]

Finally, the law provides that the receipt of a grant, contract, loan or loan guarantee under any state or federal law does not authorize any court or any public official or other public authority to require either:

1. Such individual to perform or assist in the performance of any sterilization procedure or removal of a human embryo or fetus if the individual's performance or assistance in the performance of such a procedure would be contrary to the individual's religious beliefs or moral convictions.

2. Such entity to:

   a. Make its facilities available for the performance of any sterilization procedure or removal of a human embryo or fetus if the performance of such a procedure in those facilities is prohibited by the entity on the basis of religious beliefs or moral convictions; or

   b. Provide any personnel for the performance or assistance in the performance of any sterilization procedure or removal of a human embryo or fetus by such personnel if such participation would be contrary to the religious beliefs or moral convictions of such personnel. [s. 253.09 (4), Stats.]

Generally, physicians and other health care professionals licensed by the Medical Examining Board and registered nurses licensed by the Board of Nursing are immune from civil damages for refusing to perform or participate in a sterilization procedure or the removal of a human embryo or fetus.

ASA 1 to Assembly Bill 67

ASA 1 amends the WFEA to provide that employment discrimination based on creed also specifically includes discriminating against any employee or prospective employee in a manner

prohibited by the WFEA on the basis of that person's refusal, or statement of an intention to refuse, based on his or her creed, to participate in any of the following:

1. A sterilization procedure.

2. An abortion.[3]

3. An experiment or medical procedure that destroys an in vitro human embryo or uses cells or tissue derived from the destruction of an in vitro human embryo.

4. An experiment or medical procedure on an in vitro human embryo that is not related to the beneficial treatment of the in vitro human embryo.

5. An experiment or medical procedure on a developing child in a natural or artificial womb, at any stage of development, that is not related to the beneficial treatment of the developing child.

6. A procedure, including a transplant procedure, that uses fetal tissue or organs other than fetal tissue or organs from a stillbirth, spontaneous abortion, or miscarriage.

7. The withholding or withdrawal of nutrition or hydration, if the withholding or withdrawal would result in the patient's death from malnutrition or dehydration, or complications of malnutrition or dehydration, rather than from the underlying terminal illness or injury, unless the administration of nutrition or hydration is medically contraindicated.

8. An act that intentionally causes or assists in causing the death of an individual, such as by assisted suicide, euthanasia, or mercy killing.

For purposes of the ASA 1, an "in vitro human embryo" means a human embryo, whether cryopreserved or not, living outside of a woman's body. In addition, a "human embryo" is defined as a human organism that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. The term includes a zygote but does not include a human organism at or beyond the stage of development at which the major body structures are present.

Under ASA 1, to "participate in" means to perform; to practice; to engage in; to assist in; to recommend; to counsel in favor of; to make referrals for; to prescribe, dispense, or administer drugs or devices, other than contraceptive articles, as defined in s. 450.155 (1) (a), Stats.,[4] for; or to otherwise promote, encourage, or aid.

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[3] For purposes of Assembly Bill 67 and ASA 1, an "abortion" means "the use of an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman known to be pregnant or for whom there is reason to believe that she may be pregnant and with intent other than to increase the probability of a live birth, to preserve the life or health of the infant after live birth or to remove a dead fetus." [See s. 253.10 (2) (a), Stats.]

[4] Section 450.155 (1) (a), Stats., defines contraceptive articles as "any drug, medicine, mixture, preparation, instrument, article or device of any nature used or intended or represented to be used to prevent a pregnancy."

Additionally, ASA 1 expands the provisions of current law relating to the refusal of hospitals, health care professionals, and hospital employees to participate in various procedures to apply to a refusal, based on moral or religious grounds, to participate in any of the eight activities described above. In addition, ASA 1 allows a person who may not file a claim under the WFEA and who is adversely affected by conduct that violates these provisions to bring a civil action for equitable relief, including reinstatement, or for damages, or both, and attorney's fees. For purposes of this provision of ASA 1, damages do not include "noneconomic damages" as defined under current law.[5] Such an action must be commenced within one year after the cause of action accrues.

ASA 1 also provides that licensed pharmacists are exempt from liability for damages that result from a refusal to participate in any of the eight activities if the refusal is based on religious or moral precepts. In addition, ASA 1 changes the exemptions from liability under current law for physicians and other health care professionals licensed or certified by the Medical Examining Board and registered and licensed practical nurses licensed by the Board of Nursing so that they are consistent with the exemption under ASA 1 for pharmacists.

Further, ASA 1 specifies that the Medical Examining Board, Board of Nursing, Pharmacy Examining Board, and the DRL may not take any disciplinary action against any of the following who, in writing, refuse or state an intention to refuse to participate in any of the eight activities if the refusal is based on moral or religious grounds: (1) a physician or other health care professional licensed or certified by the Medical Examining Board; (2) a registered or practical nurse licensed by the Board of Nursing; or (3) a pharmacist licensed by the Pharmacy Examining Board.

Under ASA 1, the Medical Examining Board may not take disciplinary action against a physician who makes such a refusal even if the physician refuses to transfer a patient who has executed a declaration authorizing the withholding or withdrawal of life-sustaining procedures or feeding tubes, or who has a declaration authorizing the withholding or withdrawal of life-sustaining procedures or feeding tubes, or who has executed a power of attorney for health care instrument consenting to the withholding or withdrawal of feeding tubes, to another physician who will comply with the declaration or instrument. However, under ASA 1, the Medical Examining Board may take disciplinary action against a physician who makes such a refusal if the physician refuses to transfer an incapacitated, terminally ill patient who has executed such a declaration.

Finally, under ASA 1, a physician who receives a power of attorney for health care instrument or who is notified that a patient has executed a declaration must immediately review the instrument or declaration and, if the physician intends to refuse to participate in any of the eight activities, must as soon as possible inform the patient orally and in writing about the refusal and any concerns that the physician has about the instrument or declaration. Similar requirements apply if a physician received a statement of incapacity regarding a patient who has executed a power of attorney for health care instrument. In such cases, the physician must immediately review the statement and, if the physician intends to refuse to participate in any of the eight activities, must, as soon as possible, inform the

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[5] Current law defines "noneconomic damages" as "moneys intended to compensate for pain and suffering; humiliation; embarrassment; worry; mental distress; noneconomic effects of disability including loss of enjoyment of the normal activities, benefits and pleasures of life and loss of mental or physical health, well-being or bodily functions; loss of consortium, society and companionship; or loss of love and affection."

patient's principal, orally and in writing, about the refusal and about any concerns regarding the statement.

If you have any questions or need additional information, please contact me directly at the Legislative Council staff offices.

RJC:jal:wu:rv:tlu;ksm;jal

September 7, 2003

Senator Carol Roessler
Wisconsin State Capitol
Room 8 South
P.O. Box 7882
Madison, WI 53707-7882

Dear Chairperson Roessler:

I am a registered pharmacist in southeastern Wisconsin and am writing regarding AB 67, which originally was designed to protect pharmacists such as myself as well as other health care professionals from participating in abortion and other life-ending procedures, including those abortions which occur at the chemical level. Because I believe that pharmacy is to be a totally life-saving profession, it goes against my conscience to dispense certain drugs which cause early abortion or intentional death of human life at any stage of development. Such drugs include many forms of contraception, including the birth control pill, contraceptive implants and injections, the pill used for "morning after" uses, and the IUD. Although birth control pills are supposed to and often do prevent ovulation, it is still possible for breakthrough ovulation, and thus, fertilization to occur. It is further possible that the hormones in the pill may alter the woman's uterine lining so that implantation of a newly formed embryo cannot occur and the embryo dies, which is a very early abortion. Some pills are more likely to "work" this way (that is, to prevent implantation) than others, especially when the pill is used as a "morning after" pill. However, such early abortions may occur with all types, including contraceptive implants and injections, and most definitely with the IUD.

Presently pharmacists have no protection against employment discrimination if they do not want to dispense drugs which have controversial mechanisms of action. Although there is an extremely high demand for pharmacists in our state, I have had to be very selective as to where I am willing to work because I cannot go against my conscience. Soon after I became licensed in this state, my husband and I moved to central Wisconsin where he had just accepted a job. Although pharmacy jobs in the retail sector were generally plentiful all around, I accepted a position at a newly created pharmacy in Stevens Point that served only nursing home patients. It was a 40 minute drive for me, but I knew I could work within my conscience at this pharmacy, as these patients were not prescribed any "contraceptives" which could cause chemical abortions. I actually would have preferred working in the retail sector but I didn't feel I had any protection if I requested to refrain from filling prescriptions that had abortifacient potential. I had interviewed for a store job in Wautoma prior to accepting the Stevens Point position and I did write a letter to my interviewer afterwards with my concern about dispensing such drugs, but he didn't seem to understand my position, telling me that pregnancy is defined as beginning at implantation. I didn't pursue this with him, however, because I soon found the nursing home position. Since then we have moved to southeastern Wisconsin and I am raising four young children. There are no nursing home positions fairly close to my home that I know of where I could work very part-time as I raise my children, although there are plenty of retail jobs close by.

Any health care conscious clause legislation that passes through Wisconsin's legislature needs to provide workplace protection for all health care providers, including pharmacists. If AB 67 is amended so that contraceptive articles are excluded from what health care providers would be protected from being required to provide, then the bill will basically hold no protection whatsoever for the pharmacists in this state who do not wish to participate in chemical abortion. This bill is not about taking away women's access to birth control. It is about respecting the rights of all health care providers who do not wish to participate in abortion, including chemical abortion. I ask you to seriously consider the rights of pharmacists and the preborn children they wish to protect and work to move AB 67 through in its original form.

Thank you very much.

Susan M. Grosskreuz, R.Ph.

Susan M. Grosskreuz, R.Ph.
6868 Northvue Ct.
West Bend, WI 53090

cc: Senator Tom Reynolds

Sept. 16, 2003

Senator Carol Roessler
Wisconsin State Capitol
Room 8 South
PO Box 7882
Madison, WI 53707-7882

Dear Chairperson Roessler:

I am a registered pharmacist in Wisconsin, and I am writing you in regards to AB 67, the conscience clause bill for health care workers. I understand that the original protection for pharmacists in exercising their conscience to not participate in abortions that are chemical in nature (i.e., oral contraceptives, morning-after pill, etc.) has been removed from this piece of legislation. I believe this is a step in the wrong direction. This will not only affect pharmacists like myself, but also nurses, physicians, and pharmacy technicians as well. Pharmacists are not the only ones that this issue applies to. What about the emergency room physician or nurse that doesn't feel right about dispensing the morning-after pill, but they are the "sexual assault" center for the area and their hospital mandates it? Also consider the situations when patients call the physician's office and would like refills on their oral contraceptive. The person that often authorizes these requests is the nurse, and they may not feel comfortable in this situation. And, what about the pharmacy technicians that work under pharmacists? They prepare the medication for dispensing. If they refuse to be involved, they could easily be terminated as well.

I feel that the legislation in its current form is discriminating against those of us that are just as competent and knowledgeable, and do not want to be involved in any level of abortion, be it chemical or surgical. The law has given people the "right" to participate in abortion, and I would like my right to not participate as a human being with a conscience; a medical professional that knows the truth of how these medications work and their dangers and doesn't try to hide that from the patients I serve. These medications can prevent implantation of a newly developing human embryo, and thus cause a chemical abortion (i.e. abortifacient).

I think we have to realize how many of our consciences have been desensitized to corporate America. I believe there are a lot more health professionals that would stand up and refuse to be involved, if they were rightly protected by the law, and would have no fear of losing their job, especially with the state of our economy today.

If I wanted to obtain a job in the retail sector, like Shopko, Walgreens, Osco, etc, I would be laughed out the door on the grounds of my conscientious objection. I am forced to work in a hospital where my conscience is silenced by the outside world.

I hope that you will restore AB 67 to its original form, and acknowledge the rights of every health care professional "to do no harm".

Sincerely,

Yvonne M. Kl

Yvonne Klubertanz, RPh
1030 W. Hawes Ave.
Appleton, WI 54914
WI license # 12883-040

Cc: Senator Tom Reynolds

September 17, 2003

Senator Carol Roessler

Wisconsin State Capitol

Room 8 South

P.O. Box 7882

Madison, WI 53707-7882

Dear Chairperson Roessler:

I would like to provide you with persuasive evidence in order to support truly comprehensive health care conscience clause legislation. If any health care conscience clause legislation is to move forward in the legislature, it must clearly protect pharmacists from employment discrimination if they conscientiously object to dispensing abortifacient "contraceptive" drugs and devices.

As you may know, there is good supporting evidence from primary medical literature that outlines the reality of postfertilization effects of oral contraceptives. Postfertilization effects are possible with breakthrough ovulation. Breakthrough ovulation occurs because of current low-dose estrogen (<35mcg) oral contraceptive pills. Please see the enclosed review article or retrieve the pdf document on-line at: http://archfami.ama-assn.org/cgi/reprint/9/2/126.pdf

I have a creed-based conscientious objection to participation in contraceptive articles. I am a Roman Catholic pharmacist and I have evidence to support my conscientious objection based on creed:

- "Defend the values that ennoble man. Do not be a party to attacks on human life or procreation," Holy Father tells Italian Pharmacists. *L'Osservatore Romano, N. 6-9 February 1994.*

- "All aggression against human life must be opposed; moral code must supersede laws of the marketplace." Pope tells Federation of Catholic Pharmacists. *L'Osservatore Romano, N. 46-12 November 1990.*

The following is a copy of an order I received last year from my licensing board for my refused participation in contraceptive articles:

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, that the attached Stipulation is accepted.

IT IS FURTHER ORDERED, that, Neil T. Noesen, R.Ph., is REPRIMANDED for his unprofessional conduct in this matter.

IT IS FURTHER ORDERED, that Respondent shall pay a FORFEITURE in the amount of $ 250.00, within 30 days of this order to the Department of Regulation and Licensing.

IT IS FURTHER ORDERED, that respondent shall pay COSTS in this matter in the amount of $ 300.00, within 30 days of this order to the Department of Regulation and Licensing.

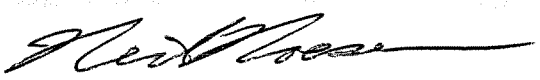
IT IS FURTHER ORDERED, that pursuant to §227.51(3), Wis. Stats., and ch. RL 6, Wis. Adm. Code, if the Board determines that there is probable cause to believe that respondent has violated any term of this Final Decision and Order, the Board may order that the license of respondent be summarily suspended pending investigation of the alleged violation.

Dated this _____, 2002.

I am contesting this order with the help of an attorney. This charge of "unprofessional conduct" is clearly an unjust discrimination on the part of the Wisconsin Department of Regulation and Licensing. This charge is unfair for Wisconsin pharmacists who have a conscientious objection to participation in contraceptive articles. We need your protection with your return of AB 67 back to its original form.

Kindly consider legislative reform of AB 67 which protects pharmacists and other health professionals (including doctors and nurses) from unfair prejudice and unjust discrimination.

Sincerely,



Neil Noesen, pharm D. (cand.)

Cc: Senator Tom Reynolds

SPECIAL ARTICLE

Postfertilization Effects of Oral Contraceptives and Their Relationship to Informed Consent

Walter L. Larimore, MD; Joseph B. Stanford, MD, MSPH

The primary mechanism of oral contraceptives is to inhibit ovulation, but this mechanism is not always operative. When breakthrough ovulation occurs, then secondary mechanisms operate to prevent clinically recognized pregnancy. These secondary mechanisms may occur either before or after fertilization. Postfertilization effects would be problematic for some patients, who may desire information about this possibility. This article evaluates the available evidence for the postfertilization effects of oral contraceptives and concludes that good evidence exists to support the hypothesis that the effectiveness of oral contraceptives depends to some degree on postfertilization effects. However, there are insufficient data to quantitate the relative contribution of postfertilization effects. Despite the lack of quantitative data, the principles of informed consent suggest that patients who may object to any postfertilization loss should be made aware of this information so that they can give fully informed consent for the use of oral contraceptives.

Arch Fam Med. 2000;9:126-133

Oral contraceptives (OCs) are among the most extensively studied and used medications in the world,[1] and are accessible without a prescription in some countries, although still virtually unavailable in others. In America, OCs have contributed to an increased acceptability of birth control,[2] although, for many patients, decisions about contraception still have moral, ethical, and religious implications.[3,4] For patients who believe that human life begins at fertilization (conception), a method of birth control that has the potential of interrupting development after fertilization (a postfertilization effect) may not be acceptable.[5,6] Postfertilization effects are operative for emergency (postcoital) contraception (when it is administered too late to prevent ovulation),[7,8] luteolytic agents (ie, RU-486),[9] and intrauterine devices,[5] and these methods therefore are unacceptable to some patients. Although postfertilization effects have been cited as a secondary mechanism of OCs,[10-12] the evidence for such effects has not been systematically reviewed. The purpose of this article was to review and grade the available evidence for postfertilization effects of OCs and discuss the implications for informed consent, based on the premise that patients to whom postfertilization effects are important have the right to make decisions based on the best available evidence.[13-15]

For Author's Comment see page 133

Our analysis of the evidence involved a review of the abstracts of all studies of OCs published since 1970 available on MEDLINE that discussed the commonly used OCs, including low-dose (<50 µg of estrogen) phasic combined oral contraceptives (COCs), low-dose monophasic COCs, and progestin-only OCs (progestin-only pills [POPs]). We also reviewed the patient handouts provided by OC manufacturers and the most recent editions of several medical textbooks and reference books.

Since there is variability in the definitions and use of terminology in reproductive medicine, we used the American

From the Department of Family Medicine, University of South Florida, Kissimmee (Dr Larimore), and Department of Family and Preventive Medicine, University of Utah, Salt Lake City (Dr Stanford).

Academy of Obstetrics and Gynecology Committee on Ethics' definitions for *fertilization*, *implantation*, *embryo*, and *preembryo*.[16] *Preembryo* is a general term that includes the human developmental stages that occur after fertilization but prior to the appearance of the primitive streak about 14 days after fertilization. From that point until the end of the eighth week after fertilization, the term *embryo* is used. Implantation is the process whereby the preembryo attaches to the endometrial lining of the uterus. This process begins 5 to 7 days after fertilization and may last several days. For this review, we defined *postfertilization effects* to include mechanisms of action that operate after fertilization to prevent a clinically recognized intrauterine pregnancy. We looked specifically for studies referencing any postfertilization effects of OCs. When many studies indicated similar findings, we listed the most recent or most methodologically sound references or other systematic or general reviews of particular subjects.

MECHANISMS OF OCs

The literature discusses several mechanisms for OCs. While the primary effect of OCs is the inhibition of ovulation via suppression of pituitary gonadotropin secretion (this mechanism is operative most of the time),[1,10,12] secondary effects are implicated at times of breakthrough ovulation to prevent clinically recognized pregnancy.[17,18] We classified these secondary effects as occurring either prefertilization or postfertilization. Secondary prefertilization effects may include alterations in cervical mucus that limit sperm penetration[2,17-20] and changes in the endometrium and fallopian tube that may impede normal sperm transport.[2,17,18,21]

Breakthrough ovulation rates vary by the form and the dose of the OC used.[2,10,12,18,22] With OCs, breakthrough ovulation is more likely with lower doses of estrogen and with imperfect rather than perfect use.[10,12,16,17,23-25] Perfect use of OCs implies taking them consistently and correctly (ie, in the correct order, on time, each and every day, and without other medications that might diminish the effectiveness of OCs). *Typical use* is described as the full range of usage patterns for OCs that actually occur in women.[1,11,12,18] While some smaller studies that evaluated small numbers of women for 6 or fewer cycles have reported breakthrough ovulation rates of near 0, studies that evaluated women for at least 6 cycles demonstrated ovulation rates ranging from 1.7%[25] to 28.6%[23] per cycle. For POPs, reported breakthrough ovulation rates range from 33%[26] to 65%.[20,27,28]

Obviously, breakthrough ovulation can result in unintended pregnancy[1,17,18]; however, the pregnancy rates with typical use vary widely and are often underestimated.[29] Unadjusted analyses of unintended pregnancies while using COCs report rates of 0.1 to 1.0 per 100 woman-years of use in perfect use and 3 per 100 woman-years in the first year of typical use.[1,10,12,17,18,20] Most of these data do not account for elective abortions. One national analysis that accounted for the underreporting of elective abortions estimated that the unintended pregnancy rates during the first year of OC use were 4% for "good compliers," 8% for "poor compliers," and up to 29% for some users.[29] Rates of pregnancy are higher with POPs than with COCs.[1,17,18] Unadjusted analyses of pregnancies while taking POPs reported rates of 0.5 to 1.0 per 100 woman-years of perfect use and 3 to 7 per 100 woman-years in the first year of typical use.[1,10,12,17,18,20] However, these rates have not been adjusted for elective abortions and are almost certainly underestimated.[29] Progestin-only pills are reported to have potent effects on both cervical mucus and the endometrium.[19-21,30,31] While this has led to speculation that "the principal mode of action is . . . to make the cervical mucus hostile to the transport of the sperm,"[17] animal model data[32] and data on ectopic pregnancy rates (reviewed below) suggest that postfertilization effects also play a role.

In theory, postfertilization effects of OCs could involve any 1 or more of the following 3 mechanisms of action: (1) A postfertilization preimplantation effect would consist of a slower transport of the preembryo through the fallopian tube, preventing the preembryo from implanting in the uterus; this could result either in the unrecognized loss of the preembryo or in an ectopic (tubal) pregnancy if the preembryo had slower tubal transport and ended up implanting in the fallopian tube. (2) A peri-implantation effect would be the alteration of the endometrium, such that a preembryo that reached the uterus was unable to successfully implant into the endometrial lining of the uterus. (3) A postimplantation effect could result from alteration of the endometrium not sufficient to prevent implantation but unfavorable for maintenance of the pregnancy; a preembryo or embryo already implanted in the endometrial lining of the uterus would be unable to maintain itself long enough to result in a clinically recognized pregnancy.

EVIDENCE FOR POSTFERTILIZATION EFFECTS

Direct evidence of postfertilization preimplantation and peri-implantation effects would require methods that directly measured the rate of fertilization and the loss of the preembryo in women taking OCs. Transcervical tubal washings have been used in women using intrauterine devices to quantify the rate of ova fertilization[33] and could theoretically be done for women taking OCs. However, there is no proven method to measure the loss of the preembryo prior to implantation, even though a number of possible methods have been investigated that involve maternal hormones that may be produced or altered after fertilization.[34-36] Probably the most promising method is the isolation of "early pregnancy factor."[37-39]

Direct evidence of a postimplantation effect on the preembryo or embryo prior to clinically recognized pregnancy would require measurement with ultrasensitive assays for β–human chorionic gonadotropin (β-HCG) or other pregnancy-related hormones.[40] Although ultrasensitive assays for β-HCG have been done with normally fertile women not using OCs,[41-44] as well as with women using nonhormonal methods of contraception,[45] we could find no such

Quality of Evidence*		
Excellent	I	Evidence obtained from at least one properly randomized controlled trial.
Very good	II.1	Evidence obtained from well-designed controlled trials without randomization.
Good to very good	II.2	Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group.
Good	II.3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.
Poor to good	III	Opinion of respected authorities based on clinical experience, descriptive studies and case reports, or reports of expert committees.

*Adapted from Berg.[46]

studies in women using OCs. Despite the lack of these data, at least 3 lines of evidence have been suggested to support the hypothesis that 1 or more postfertilization effects are operative in at least some women taking OCs. Using a standard quality of evidence table[46] (**Table**), we graded the available evidence.

Endometrial Changes That May Affect Endometrial Receptivity

Oral contraceptives directly affect the endometrium.[1,10,12,20,21] These effects have been presumed to render the endometrium relatively inhospitable to implantation or to the maintenance of the preembryo or embryo prior to clinically recognized pregnancy by producing a predecidual or decidualized endometrial bed with diminished thickness and with widely spaced, exhausted, and atrophied glands; by altering the cellular structure of the endometrium, leading to the production of areas of edema alternating with areas of dense cellularity[18,20,21]; and by altering the biochemical and protein composition of the endometrium.[47]

Although these changes are consistently seen in women taking OCs, there is currently no direct evidence to link these changes to preembryo or embryo loss in women taking OCs. However, this hypothesized postfertilization effect seems to be so well accepted that in many medical articles and textbooks it has been explicitly listed as the third mechanism of OCs (after suppressing ovulation and prefertilization effects).[1,10,17,18] For example, the Food and Drug Administration–approved product information for OCs in the *Physicians' Desk Reference* states,

> Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus, which increase the difficulty of sperm entry into the uterus, and changes in the endometrium, which reduce the likelihood of implantation.[11]

An independent clinical pharmaceutical reference also contains this assertion.[12] We considered this level III (poor to good) evidence (Table).

To assess the clinical significance of an altered endometrium, it was helpful to examine data that compared endometrial thickness with the receptivity of the endometrium to preembryos during in vitro fertilization procedures. Magnetic resonance imaging scans of the uteri of women reveal that the OC users have endometrial linings that are consistently thinner than the endometrial linings of nonusers,[48-50] up to 58% thinner.[51] Of the first 4 ultrasound studies published, the first did not find a relationship between endometrial thickness and in vitro fertilization implantation rates[52]; however, subsequent studies noted a trend,[53,54] and one demonstrated that a decreased thickness of the endometrium decreased the likelihood of implantation.[55] Larger, more recent, and more technically sophisticated studies[56-65] all concluded that endometrial thickness is related to the functional receptivity of the endometrium. Furthermore, when the endometrial lining becomes too thin, then implantation does not occur.[56-58,64,65] The minimal endometrial thickness required to maintain a pregnancy in patients undergoing in vitro fertilization has been reported, ranging from 5 mm[55] to 9 mm[65] to 13 mm,[53] whereas the average endometrial thickness in women taking OCs is 1.1 mm.[50] These data would seem to lend credence to the Food and Drug Administration–approved statements that " . . . changes in the endometrium . . . reduce the likelihood of implantation."[11] We considered this level II.2 (good to very good) evidence (Table).

Integrin Changes Affecting Fallopial Tube and Endometrial Receptivity for Implantation

Integrins are a family of cell adhesion molecules that are accepted as markers of uterine receptivity for implantation.[66,67] Temporal and spatial expression of these endometrial peptides is believed to contribute to the establishment and maintenance of a cyclical endometrial receptivity. Three cycle-dependent integrins ($\alpha1\beta1$, $\alpha4\beta1$, $\alpha V\beta3$) have been shown to be " . . . coexpressed apparently only for a brief interval of the cycle that corresponds with the putative window of maximal uterine receptivity" and " . . . have emerged as reliable markers of normal fertility."[68] Of these 3, the $\alpha V\beta3$ integrin seems "to be an excellent marker to study the molecular events leading to the establishment of uterine receptivity and successful implantation."[68,69] These 3 integrins are conspicuously absent in the endometrium of most patients with luteal phase deficiency, endometriosis, and unexplained infertility.[68]

In addition, integrin expression is significantly changed by OCs. Integrins have been compared using endometrial biopsy specimens from normally cycling women and women taking OCs. In most OC users, the normal patterns of expression of the integrins are grossly altered, leading Somkuti et al[68] to conclude that the OC-induced integrin changes observed in the endometrium have functional significance and provide evidence that reduced endometrial receptivity does indeed contribute to the contracep-

tive efficacy of OCs. They hypothesized that the sex steroids in OCs alter the expression of these integrins through cytokines and therefore predispose to failure of implantation or loss of the preembryo or embryo after implantation. We considered this level II.3 (good) evidence (Table).

Integrins have also been identified in the fallopian tube.[69] Of interest, the αV subunit is expressed in the fallopian tube epithelium throughout the cycle, but the β3 subunit is only upregulated during the period of endometrial receptivity. Therefore, it has now been postulated that the normal tubal epithelium also has an implantation window that "... affords the opportunity for trophoblast attachment should a 5-7 day preembryo be unduly retained in the tube."[69] As discussed earlier, one of the postulated actions of the OCs is a slowing of tubal peristalsis (via smooth muscle relaxation)[70]; therefore, a reduction in tubal peristalsis that is associated with an upregulation of the αVβ3 integrin in the epithelium of the fallopian tube could theoretically lead to an increased risk of ectopic pregnancies in women taking OCs.

If breakthrough ovulation occurs while using the COC, then to some extent ovarian and blastocyst steroidogenesis could theoretically "turn on" the endometrium, causing it to normalize prior to implantation in the ovulatory cycle. However, after discontinuing use of COCs, it usually takes several cycles for a woman's menstrual flow to approach the volume of women who have not taken hormonal contraception,[71] suggesting that the endometrium is slow to recover from its COC-induced atrophy. Furthermore, in women who have ovulated secondary to missing 2 low-dose COCs, the endometrium in the luteal phase of the ovulatory cycle has been found to be nonsecretory.[23]

Increased Extrauterine Pregnancy to Intrauterine Pregnancy Ratio

If the action(s) of OCs on the fallopian tube and endometrium were such as to have no postfertilization effects, then the reduction in the rate of intrauterine pregnancies in women taking OCs should be proportional to the reduction in the rate of extrauterine pregnancies in women taking OCs. If the effect of OCs is to increase the extrauterine-to-intrauterine pregnancy ratio, this would indicate that one or more postfertilization effects are operating. All published data that we could review indicated that the ratio of extrauterine-to-intrauterine pregnancies is increased for women taking OCs and exceeds that expected among control groups of pregnant women not currently using OCs. These case-controlled series come from 33 centers in 17 countries and include more than 2800 cases and controls.[72-77] The odds ratios in these studies ranged from 1.7 (95% confidence interval [CI], 1.1-2.5)[72] to 1.8 (95% CI, 0.9-3.4)[73] to 4.3 (95% CI, 1.5-12.6)[74] to 4.5 (95% CI, 2.1-9.6)[75] to 13.9 (95% CI, 1.8-108.3).[76] The letter by Job-Spira et al[74] seems to represent the same data set of 279 cases and controls as the study by Coste et al.[76] The meta-analysis by Mol et al[73] includes 2 of the publications,[72,75] but one of these may include women taking POPs.[72] Therefore, of the 5 publications, only 2 allow review of the association of COCs with ectopic pregnancy.[75,76] These 2 studies from 7 maternity hospitals in Paris, France, and 3 in Sweden involved 484 women with ectopic pregnancies and 289 pregnant controls and suggest that at least some protection against intrauterine pregnancy is provided via postfertilization preimplantation effects. We recognize that studies that have used nonpregnant controls have not shown a risk of increased ectopic pregnancy for users of COCs. In our review, we restricted our analysis to studies using pregnant controls, because we concur with researchers[73,76] in this field that "... when considering the situation where a woman became pregnant during contraceptive use, one should focus on pregnant controls."[73] Therefore, COC use seems to be associated with an increased risk of ectopic implantation or unrecognized loss of preembryos. We considered this level II.2 (good to very good) evidence (Table).

Ectopic pregnancy is a particular form of postfertilization loss that involves substantial risks to the woman, and thus the absolute risk of ectopic pregnancy for women taking OCs will be of interest to clinicians and patients. Converting a relative risk of ectopic pregnancy to an absolute risk has many inherent difficulties that have been reviewed elsewhere.[78] Nevertheless, adapting the method suggested by Franks et al[78] would allow one to predict that the ectopic pregnancy rate for women taking OCs would be the product of 3 factors: (1) the overall pregnancy rate per 1000 woman-years among those taking OCs, (2) the proportion of extrauterine pregnancies compared with all pregnancies for a comparable control population not taking OCs, and (3) the relative risk for ectopic pregnancy in women taking OCs compared with the control population, which may be estimated by the odds ratio from case-control studies. For factor 1, Potter[29] suggests 40 for good compliers and 80 for poor compliers. For factor 2, the proportion of ectopic pregnancies in the 1990s is estimated to range from 1 in every 56[79] to 64[80,81] pregnancies (0.0156 to 0.0179). A reasonable range for factor 3 would be 1.1 to 13.9, based on the studies discussed above. This model would predict an absolute risk ranging from 0.7 ($40 \times 0.0156 \times 1.1$) to 19.9 ($80 \times 0.0179 \times 13.9$) ectopic pregnancies per 1000 woman-years. We could only find one study, from Zimbabwe, which reported an absolute risk of ectopic pregnancy in women taking OCs of 0.5[82] per 1000 woman-years.

The risk of ectopic pregnancy is higher with POPs, and ectopic pregnancy has been discussed at length by a number of investigators as a clinically significant potential complication of POPs.[82-84] The odds ratio of an extrauterine pregnancy for a woman taking a POP (compared with pregnant controls) was reported in only one study and was 79.1 (95% CI, 8.5-735.1).[74] Assuming an overall clinical pregnancy rate of 30 to 70 per 1000 woman-years, this equates to a predicted absolute risk of 4 to 99 ectopic pregnancies per 1000 woman-years ([30 or

70] × [0.0156 or 0.0179] × [8.5 or 79.1]) in women taking POPs. This is reasonably concordant with absolute rates of ectopic pregnancy in women taking POPs, which have been reported to range from about 3[82,83,85] to about 20[84,86] per 1000 woman-years.

Data from case-controlled series demonstrate that women with clinically recognized pregnancy are no more or less likely to miscarry based on whether they were taking an OC after their pregnancy was clinically recognized.[87-90] However, the epidemiology, biology, and recognized risk factors of clinically recognized embryo or fetal loss (spontaneous abortion after clinically recognized pregnancy) do not seem to apply to early (unrecognized) preembryo or embryo loss, as the available evidence suggests that the mechanisms of early establishment and maintenance of pregnancy and later maintenance of pregnancy are qualitatively and substantially different.[90]

COMMENT

We found the evidence supporting postfertilization effects for OCs in the prevention of clinically recognized pregnancy to range from poor (level III) to very good (level II.2). Specifically, evidence based on alterations in endometrial biochemistry and histology (level III), evidence based on endometrial thickness and endometrial receptivity from research studying in vitro fertilization (level II.2), and evidence based on endometrial integrins (level II.3) all support the possibility of peri-implantation or postimplantation effects. Furthermore, evidence based on ectopic-to-intrauterine risk ratios from multiple case-control studies (level II.2) supports the possibility of postfertilization preimplantation, peri-implantation, or postimplantation effects. However, we could identify few data that would assist in quantifying these postfertilization effects. It seems likely that for perfect use of COCs, postfertilization mechanisms would be likely to have a small but not negligible role. For POPs, COCs with lower doses of estrogen, and imperfect use of any OCs, postfertilization effects are likely to have an increased role. In any case, the medical literature does not support the hypothesis that postfertilization effects of OCs do not exist.

Despite the evidence, which suggests that postfertilization effects for OCs are operational at least some of the time, and the fact that a postfertilization mechanism for OCs is described in the *Physicians' Desk Reference*,[11] in *Drug Facts and Comparisons*,[12] and in most standard gynecologic, family practice, nursing, and public health textbooks, we anecdotally find that few physicians or patients are aware of this possibility. Therefore, we believe that the potential for postfertilization effects is probably not routinely presented to patients as part of their informed consent to use an OC. Furthermore, it is of concern to us that only one of the many OC patient information handouts we and others[5] have reviewed, including those produced by the OC manufacturers, mentions the possible postfertilization mechanism, despite the fact that this information is nearly always included in the professional labeling of these same OCs.

Since there is evidence to support the existence of postfertilization effects and because it is impossible to know in advance which patients would find the potential for this effect objectionable, we believe that the lack of information regarding postfertilization effects in patient information materials about OCs represents a potential failure to provide complete informed consent. Furthermore, if this mechanism of an OC violates the moral requirements of a woman, then failure to disclose this information seriously jeopardizes her autonomy. If information about the mechanism of an OC is deliberately withheld or misstated, then an unethical deception occurs. Failure to disclose information that might lead a patient to choose a different method of treatment is generally considered to be unethical.[12,13] Therefore, it seems clear to us that failure to inform patients of a possible postfertilization mechanism of an OC is a failure to provide informed consent.

PROVIDING INFORMED CONSENT

Many reproductive scientists have defined pregnancy as occurring at the point of or at some point after implantation.[16,91,92] However, this definition does not change the fact that some patients, for personal, scientific, moral, or religious reasons, identify the start of human life at fertilization. For such patients, a form of contraception that allows fertilization and then causes loss of the preembryo or embryo may be unacceptable. Regardless of the personal beliefs of the physician or provider about the mechanism of OCs, it is important that patients have information relevant to their own beliefs and value systems.

However, the objective presentation of the potential for postfertilization effects of OCs may be complex; there are a variety of potential interpretations of the postfertilization effects depending on which aspect is emphasized: (1) One could state that OCs may significantly reduce the absolute risk per woman-year of any possible postfertilization loss in the same way that they reduce the absolute clinical pregnancy rate.[78] For some women or medical personnel who believe that human life begins at fertilization, this view might render OCs, even with postfertilization loss, morally acceptable. (2) One could emphasize that once fertilization has occurred, OCs may cause at least an occasional postfertilization loss, regardless of the rate of fertilization. For some women or medical personnel who believe that human life begins at fertilization, the view that any postfertilization loss could be attributed to the effects of OCs and therefore could be considered induced rather than natural may render OCs morally unacceptable to use, even if the absolute frequency of such an event is very low.

Medical colleagues have suggested to us that postfertilization loss attributed to OCs would not need to be included in informed consent until it is either definitely proven to exist or proven to be a common event. However, rare but important events are an essential part of other informed consent discussions in medi-

cine, primarily when the rare possibility would be judged by the patient to be important. For example, anesthesia-related deaths are extremely rare for elective surgery (<1:25 000 cases); nevertheless, it is considered appropriate and legally necessary to discuss this rare possibility with patients before such surgery because the possibility of death is so important. Therefore, for women to whom the induced loss of a preembryo or embryo is important, failure to discuss this possibility, even if the possibility is judged to be remote, would be a failure of informed consent. Others feel that an overemphasis of possible postfertilization effects might make women choose a less-effective method of contraception and therefore increase the incidence of unplanned pregnancy. Both of these views fail to acknowledge the value of a woman's autonomy in making decisions based on informed consent. During informed consent discussions, overemphasis of any single possible risk may not result in appropriate informed consent; however, neither does choosing to not mention the possible risk result in adequate informed consent. Therefore, discussion of this potential risk should occur and should be kept within the perspective of the available medical evidence.

One possible approach to this complex issue might be to inquire of the patient whether she desires this information. The physician or provider might say, for example: "Most of the time, the pill acts by preventing an egg from forming. This prevents pregnancy. However, women on the pill can still sometimes get pregnant. Some doctors think that the pill may cause the loss of some of these pregnancies very early in the pregnancy, before you would even know you were pregnant. Would knowing more about this possibility be important to you in your decision about whether to use the pill?"

If the answer is yes, further explanation of the issues would be indicated and should occur in terms that are as understandable as possible. Proper informed consent requires patient and physician comprehension of information, the disclosure of this information, and the sharing of interpretations.[14,15] If any mechanism of any OC violates the morals of any particular woman, the failure of the physician or care provider to disclose this information would effectively eliminate the likelihood that the woman's consent was truly informed[13,14,93] and would seriously jeopardize her autonomy.[13]

Furthermore, there is a potential for negative psychological impact on women who believe human life begins at fertilization, who have not been given informed consent about OCs, and who later learn of the potential for postfertilization effects of OCs.[94] The responses to this could include disappointment, anger, guilt, sadness, anger, rage, depression, or a sense of having been violated by the provider.[5] Further research is necessary to identify the exact frequency of postfertilization effects of OCs.

CONCLUSIONS

The available evidence supports the hypothesis that when ovulation and fertilization occur in women taking OCs, postfertilization effects are operative on occasion to prevent clinically recognized pregnancy. Physicians should understand and respect the beliefs of patients who consider human life to be present and valuable from the moment of fertilization. Since it would be difficult to predict which patients might object to being given an OC if they were aware of possible postfertilization effects, mentioning the potential for postfertilization effects of OCs to all patients and providing detailed information about the evidence to those who request it is necessary for adequate informed consent.

Accepted for publication March 18, 1999.

We thank John R. Hartman, MD, Chris Kahlenborn, MD, G. Gayle Stephens, MD, William Toffler, MD, and Randy Alcorn, MS, for their help with conceptual development of this article and for identifying important references.

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Author's Comment

I have prescribed "the Pill" since 1978. My wife and I used the Pill for years, having no moral concerns about it. Then, in 1995 my friend and practice partner John Hartman, MD, showed me a patient information brochure—given to him by a friend—that claimed the Pill had a postfertilization effect causing " . . . the unrecognized loss of preborn children." John asked me if I had ever heard of such a thing. I had not. I did read the brochure and its claims seemed to be outlandish, excessive, and inaccurate. So, I decided to begin a literature search to disprove these claims to my partner, myself, and any patients who might ask about it. The more research I did, the more concerned I became about my findings. I called researchers around the country and interviewed them. During this process I met Joe Stanford, MD. Joe volunteered to assist in the research that ultimately became this systematic review. We were concerned enough about our findings and about the fact that so many of our colleagues and patients seemed to share our ignorance about this potential effect that we presented the preliminary results of our research at a number of research forums, just to see if we were off base. Most of the reviewers suggested that, although this evidence was new to them (as it was to us), it seemed accurate and not off target. Furthermore, several said that they thought it would change the way family physicians informed their patients about the Pill and its potential effects.

The most difficult part of this research was deciding how to apply it to my practice. I discussed it with my partners, my patients, ethicists I know and respect, and pastors in my community. I studied the ethical principle of double effect and discussed the issue with religious physicians of several faiths. Finally, after many months of debate and prayer, I decided in 1998 to no longer prescribe the Pill. As a family physician, my career has been committed to family care from conception to death. Since the evidence indicated to me that the Pill could have a postfertilization effect, I felt I could no longer, in good conscience, prescribe it—especially since viable alternatives are available. The support and encouragement that my partners, staff, and patients have given me has been unexpectedly affirming. It seems that my patients have appreciated the information I have given them. Many have been surprised or even shocked (as I was) to learn about this potential effect. Many of my patients have chosen to continue taking the Pill, and we have physicians in our practice and community who will prescribe it for them. Patients who take the Pill tell me that they are much more careful with their compliance. Others have chosen other birth control options—especially one of the modern methods of natural family planning. So, this is research that has changed my soul and my practice. It has been an extraordinarily difficult issue with which I have had to wrestle. I suspect it will be so for many who thoughtfully read and consider the evidence contained in this review.

Walter L. Larimore, MD
Kissimmee, Fla

FEB 03 2004

AB 67

I just wanted to thank you for listening to physicians regarding AB 67. The changes that were made really do increase clarity.

This is such a timely and important issue that I hope all parties will eventually come to an agreeable solution. A start on such a solution may be found at the Wisconsin Medical Society meeting this April, at which time we will consider a resolution on futility. It is modeled after the Texas Advanced Directive Act of 1999 and proposes a way to resolve disputes in an extra-judicial process.

Other projects that I would some day like to work on are reciprocity of health care power of attorneys throughout the states and an improvement in the language (and length) of our current HCPOA document.

Sincerely,

Kay Heggestad

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