JL (6.10.15)

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To: The European court of Human Rights

Re: Third-party intervention in the case of Dubská and Krejzová v The Czech Republic,

Applications nos. 28859/11 and 28473/12 in the Grand Chamber

Enclosed is the intervention of The International Study Group of the World Association of Perinatal Medicine and the International Academy of Perinatal Medicine. A hard copy will be sent to you. Do not hesitate to contact me if I can provide any further assistance in this matter.

With best wishes,

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The International Study Group of the World Association of Perinatal Medicine and the International Academy of Perinatal Medicine herewith presents its

Third-party intervention in the case of *Dubská and Krejzová v The Czech Republic*, Applications nos. 28859/11 and 28473/12 in the Grand Chamber

The Interveners

The World Association of Perinatal Medicine and the International Academy of Perinatal Medicine include in their membership scientific and clinical leaders in the medical care of pregnant women, fetal patients, and neonatal patients. The Association and Academy advocate for the evidence-based clinical care of pregnant, fetal, and neonatal patients. The members of the Association and Academy are predominantly from countries included in the Council of Europe.

The members are all leading professors of perinatal medicine: Frank A. Chervenak, M.D., Weill Medical College of Cornell University, New York, New York, United States; Brigit Arabin, M.D., Philipps University, Marburg, Germany; Malcolm I. Levene, M.D., University of Leeds, United Kingdom; Robert L. Brent, M.D., Ph.D., Thomas Jefferson University, Philadelphia, Pennsylvania, United States; Amos Grünebaum, M.D., Weill Medical College of Cornell University, New York, New York, United States; and Laurence B. McCullough, Ph.D., Baylor College of Medicine, Houston, Texas, United States.

This International Study Group began its scientific work on planned home birth at a 2013 scientific meeting at the National Academy of Medicine of the U.S. National Academies of Science, Engineering, and Medicine. The International Study Group has, to date, published scientific papers in the international peer-reviewed literature on the outcomes of planned home birth in the United States, as well as ethics papers in the international peer-reviewed literature on the professional responsibilities of physicians regarding planned home birth. These papers represent the most clinically comprehensive and ethically rigorous analysis of the clinical and ethical dimensions of planned home birth.[1,2,3,4,5,6,7,8,9,10,11] In addition, the International Study Group has made scientific and ethics presentations at international medical congresses, the majority of which have met in Europe.

The International Study Group is internationally respected for its evidence-based scientific analyses of the outcomes of planned home birth for pregnant women, fetus, and newborn children. These analyses have called into question the safety of planned home birth and the reliability of selection of "low risk" women for planned home birth. These analyses have also called into question whether the experience in countries with advanced planned home birth systems, such as that in The Netherlands and the United Kingdom, applies to other countries without such well-established systems for planned home birth, such as the United States and the Czech Republic.

Definitions of clinical and statistical terminology appear in footnotes. Sources, i.e. expert study reports used and referred to, appear in endnotes.

Summary Statement

According to the results of our studies, planned home birth involves unnecessary, preventable increased risks to pregnant, fetal, and neonatal patients. Pregnant women who continue their pregnancies to term freely assume ethical obligations to their fetus and soon-to-be-born child to select a site for delivery that is not unnecessarily risky. The pregnant woman's autonomy is therefore justifiably constrained by such ethical obligations.

Intervention

This intervention has two main parts. The first presents the results of our scientific studies of planned home birth in the United States. The second presents the results of our ethical studies of planned home birth in the United States and European countries.

I. SCIENTIFIC STUDIES OF PLANNED HOME BIRTH IN THE UNITED STATES

We have published a series of scientific studies concerning the safety of birth in relation to various birth settings and birth attendants in the United States.[12] These are the largest and most comprehensive studies of their kind to date and used data on more than 13 million births. These studies were not reflected in the Chamber judgment.

Our studies use the national data set on births in the United States of the Centers for Disease Control (CDC) of the U.S. Department of Health and Human Services. This data set is generally the preferred source for infant and neonatal mortality in the United States (US). The CDC linked birth/infant death files[i] are publicly available at http://www.cdc.gov/nchs/data_access/vitalstatsonline.htm and contain detailed information for the approximately 4 million births in the United States each year, including birth setting, birth attendant, and neonatal outcomes. The publicly accessible CDC data set is largest, most comprehensive and scientifically reliable source of data on the outcomes of births in the United States. As regards its extent, there is no comparable data set in any other country in the world. This factor considerably strengthens the reliability of the research results. The smaller a data set is, the more limited outcomes it entails.

The 2006–2009 period linked birth/infant deaths data set, which is the most currently available, was analyzed in our studies to determine: the relative risk of 5-minute Apgar scores[ii] of zero; the relative risk of seizures and other adverse neurological outcomes;[iii] and the relative risk of neonatal mortality.[iv] We analyzed outcomes for singleton births from term pregnancies (≥37 weeks and newborn weight ≥ 2,500 grams) free of documented congenital malformations by birth setting (hospital vs. home) and provider: hospital midwife; hospital physician; and home midwife. The reference set for our analyses has been certified nurse midwives in U.S. hospitals, to allow for direct comparison of midwife-attended planned home birth and midwife-attended hospital birth.

Data Documenting that Planned Home Birth in the United States is Unsafe

Our studies showed that there is an increased relative risk of 5-minute Apgar scores of zero, of seizures and other adverse neurological outcomes,[13] and of neonatal mortality for planned home birth when compared to hospital births.[14]

[i] Period linked files use all births in a year as the denominator and all deaths in a year as the numerator, regardless of when the birth occurred (e.g. if the birth was in late 2008 then neonatal death could have been 2008 or 2009 but counted in the 2008 numerator only if the death occurred in 2008).

[ii] The Apgar score provides a physiologic profile of the neonate and has been used throughout the world for the past 50 years to guide clinical decisions about neonatal intervention. An Apgar score of zero at five minutes is virtually synonymous with the death of the neonate.

[iii] These are indicators of potential developmental disability.

[iv] Preventable neonatal mortality is an unacceptable outcome.

A five-minute Apgar score of zero in virtually all cases indicates still birth. The relative risk (RR) of this outcome for planned home births attended by midwives when compared to midwife-attended hospital births is 10.55.[v]

The occurrence of seizures and other adverse neurological outcomes is clinically significant because they are closely associated with long-term disabilities. The relative risk for this outcome for planned home births attended by midwives when compared to midwife-attended hospital births is 3.8.

Neonatal mortality means that a live-born infant died within the first four weeks of life. The relative risk for this outcome for planned home births attended by midwives when compared to midwife-attended hospital births is 3.87.

These adverse outcomes are preventable by planned hospital birth and are therefore unnecessary.

Data Documenting Poor Risk Assessment by Midwives Attending Planned Home Birth

Our study showed that in the United States midwife-attended planned home births had the following risk factors: breech presentation,[vi] 0.74% (odds ratio [OR],[vii] 3.19); prior cesarean delivery, 4.4% (OR, 2.08); twins, 0.64% (OR, 2.06) and gestational age 41 weeks or longer, 28.19% (OR, 1.71). All 4 perinatal risk factors were significantly higher among midwife-attended planned home births when compared with certified nurse midwives-attended hospital births.[15]

This poor assessment of perinatal risk is preventable by planned hospital birth and is therefore unnecessary.

Data Documenting Inflation of 5-Minute Apgar Scores by Midwives Attending Planned Home Births

Newborns delivered by midwives at home had a significantly higher likelihood of a 5 min maximum Apgar score of 10 than those delivered in a hospital [OR 29.19].[16]

Our study shows an inexplicable bias of high 5 min Apgar scores of 10 in home deliveries. Midwives delivering at home assigned a significantly higher proportion of Apgar scores of 10 when compared to midwives or physicians delivering in the hospital. Studies that have claimed the safety of out-of-hospital deliveries by using higher mean or high cut-off 5 min Apgar scores and reviews based on these studies should be treated with skepticism by obstetricians and midwives, by pregnant women, and by policy makers. The continued use of studies using higher mean or high cut-off 5 min Apgar scores as the basis for advocating for the safety of planned home birth, given the unexplained higher rate of Apgar scores of 10, is inappropriate. It appears that many home birth midwives are mistakenly or even intentionally assigning Apgar scores of 10.

Summary

The data that we have presented in this section support the conclusion that planned home birth has higher risks of neonatal mortality and serious morbidity that can be prevented by planned hospital birth.

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[v] Relative risk measures the increased likelihood of an event occurring compared to another event. A relative risk of 10.55 for an Apgar score of zero at five minutes means that babies born at home are 10.55 times more likely to die than babies delivered by a midwife in a hospital.

[vi] In a breech presentation the fetus's feet or buttocks are delivered first, rather than the head.

[vii] An odds ratio is a measure of the relative increase of likelihood of occurrence of an event compared to another event.

II. Ethical Studies of Planned Home Birth in the United States and European Countries

We have published a series of papers using an evidence-based approach to the ethics of professional responsibility in planned home birth when compared to planned hospital birth.[17] We have published criteria for rigorous argument in ethics, to which our published work on the ethics of planned home birth conforms.[18] The professional ethics of healthcare is therefore not a matter of the personal opinion of individuals but of evidence-based, rigorous argument that clearly identifies relevant ethical concepts and their implications for professional clinical practice.[19]

The advocates of planned home birth emphasize (1) patient safety, (2) patient satisfaction, (3) cost effectiveness, and (4) respect for women's rights. The purposes of this part are to critically evaluate each of these claims and to identify professionally appropriate responses of obstetricians and other concerned physicians to each claim and therefore to planned home birth.

Patient Safety

Discussion of patient safety should be based on evidence about obstetric outcomes.[20] The American College of Obstetricians and Gynecologists (ACOG) accepts the reported finding that there is a twofold to threefold risk of neonatal death from planned home vs. hospital birth. ACOG takes the view that pregnant women should be informed about this risk.[21]

The Royal College of Obstetricians and Gynaecologists (RCOG) and Royal College of Midwives (RCM) Joint Statement goes further and claims that planned home birth is a "safe option for many women."[22] This claim does not withstand close scrutiny for planned home birth without immediate access to hospital-based care. Such settings are unavoidably at risk for transport to the hospital. It is not surprising that the perinatal mortality[viii] rate was reported to be more than 8 times higher when transport from home to an obstetric unit was utilized. As clinicians we have all experienced that unavoidable delay involved in even the best transport systems from home to hospital and even from labor and delivery to the operating room results in increased risks of mortality and morbidity for pregnant, fetal, and neonatal patients.

Maternal and fetal necessity for transport during labor is often impossible to predict and indications include failure for labor to progress, unbearable labor pain, fetal malpresentation, increasing maternal temperature, suspicious fetal heart-rate tracings, abrupt deterioration of fetal heart rate, uterine rupture, acute bleeding, placental abruption, vasa previa,[ix] acute sepsis, and cord prolapse. For unpredictable, extremely sudden complications, even rapid transport may not prevent the fetus or pregnant woman from death or severe harm, such as sudden cardiopulmonary arrest, shoulder dystocia,[x] or maternal exsaguination.

Postnatal reasons for transport include lacerations of the vagina or cervix , sphincter rupture,[xi] uterine atony[xii] and placenta accreta, increta or percreta.[xiii] In patients with severe hemorrhage and placental

[viii] Perinatal mortality includes death of the fetus before and during labor and of the neonate after live birth.

[ix] Vasa previa is complication of pregnancy in which a fetal blood vessel presents before the fetal head and can be ruptured during vaginal delivery.

[x] Shoulder dystocia occurs when the fetal shoulders have difficulty fitting into the birth canal. Vaginal delivery may result in permanent nerve damage.

[xi] Sphincter rupture is damage done to the muscle that controls anal continence of the pregnant woman.

[xii] Uterine atony occurs when the uterus does not contract and catastrophic hemorrhage can occur with possible maternal death.

[xiii] These conditions occur when the placenta to some degree grows into the uterine wall and can result catastrophic hemorrhage with possible maternal death.

problems the pregnant woman may already be in shock when arriving at a hospital. Even though operative and shock treatment can be immediately instituted, death may nevertheless sometimes occur.

Neonatal reasons for transport are myriad and include unexpected very low or very high birth weight, neonatal depression, signs of respiratory distress, unexpected malformations, and acute sepsis. In the general population, the incidence of common problems, such as major malformations, prematurity, and severe fetal growth restriction is not inconsequential. Moreover, the best screening procedures, even when optimally performed, sometimes fail to detect these high-risk conditions. Given the severity and frequency of reasons for transport, even a very low rate of emergency transport should prompt considerable concern. This has been proven by a review of perinatal deaths in planned home births in Southern Australia where inappropriate inclusion of women with risk factors resulted in inadequate fetal surveillance during labor.[23]

The recent Birthplace in England prospective cohort study reported transport rates from non-obstetric units to the hospital of 36 to 45% for nulliparous women and 9 to 13% for multiparous women.[24] For the primary outcome measure of perinatal mortality and specific morbidities, there was an adjusted odds ratio of 1.59 for women "without any complicating factor at the start of care in labour" for planned home vs. planned obstetric unit births. The adjusted odds ratio was 1.75 for the primary outcome for planned home vs. planned obstetric unit births for nulliparous women, which increased to 2.8 when restricted to nulliparous women with no complications at the start of labor. The 59 to 75% increase in a poor primary outcome is attributable to the delay in access to hospital care from transport time. Only in the online appendix were so called "events" elucidated. In the primary outcome population, intrapartum stillbirths[xiv] and early neonatal deaths accounted for 13%, neonatal encephalopathy for 46%, meconium aspiration syndrome for 30%, brachial plexus injury for 8%, and fractured humerus or clavicle for 4% of events. It is concluded that these "results support a policy of offering healthy nulliparous and multiparous women with low risk pregnancies a choice of birth setting." We contend that this view is irrational and cannot be supported in light of the reported adverse outcomes for birth outside of an obstetric service.

In the Netherlands there is a long tradition of optimally organized home birth, with well-trained midwifes and a transport system with short distances to hospitals. Nonetheless, 49% of primiparous and 17% of multiparous women are transported during labor. The most frequent indications are the need for pain relief (which is subjective and possibly influenced by anxieties to continue with the delivery at home) and prolonged labor. Women who are transferred to a hospital have a significantly higher rate of operative vaginal delivery and secondary cesarean delivery (RR: 1.42 /1.2) and a higher rate of peridural anesthesia (RR: 1.45). Of all primiparous women transported in the Netherlands to a hospital due to prolonged labor, two thirds need pain treatment.[25]

De Neef et al. analyzed the intention to deliver either at home (45%), under guidance of a midwife within a hospital (44%) or under guidance of an obstetrician in a hospital (11%) in Dutch primiparous women in the first trimester. The reality was that only 17% of these women delivered at home, 10% delivered under the guidance of a midwife in an obstetric unit, but 73% delivered in a hospital under the care of an obstetrician. The authors logically conclude that patients have to be informed about these numbers and the high transport rates.[26] Such information is essential for pregnant women to make good decisions about the site of delivery. In Germany, midwives are obligated to inform their patients about the distance from the freestanding midwifery unit (or home) to the nearest hospital obstetric unit and

[xiv] Intrapartum stillbirth means that the fetus dies during labor before delivery and is delivered dead.

the approximate average time of transport. Midwives are also obligated to document this information in the informed consent form and in the patient's record.

A study from South Australia reported that home births between 1991 and 2006 accounted for only 0.38% of 300,011 births in spite of an average long distance from home to a perinatal center. The perinatal mortality rate of non-hospital deliveries was similar to that for planned hospital births (7.9 v 8.2 per 1000 births). However, there was a 7-fold higher risk of intrapartum death and a 27-fold increased risk of death from intrapartum asphyxia.[27] This shows that the perinatal mortality rate may obscure significant differences between asphyxia and intrapartum death resulting from home birth. Prenatal deaths are obviously increased in pregnancies followed by hospital perinatal centers due to obligate referral of high risk patients, including fetal patients with malformations, to these centers.

Reporting from United States, Ecker and Minkoff focus on the absolute risk of planned home birth, rather than the relative risk, and claim that the "potentially small increment in absolute risk that a particular patient choice carries" is ethically acceptable.[28] The data above support a different clinical and ethical assessment: the increment is far from small and ethically acceptable in the clinical setting where there is zero tolerance for preventable risk of adverse outcomes. We disagree with Ecker and Minkoff and all others who judge the adverse outcomes of planned home vs. hospital birth to be ethically acceptable. The professional responsibility response demands adherence to accepted standards of care.

The adverse outcomes described above can be sometimes reduced in their incidence by access to timely cesarean delivery. In the United States there has been a "rule" of 30 minutes from "decision to incision." ACOG has revised this to state that "when a decision for operative delivery in the setting of a Category III EFM[xv] tracing is made, it should be accomplished as expeditiously as feasible."[29] In Germany, a 20-minute interval from decision to delivery is used for quality assessment of perinatal centers.

None of these standards can be consistently met if pregnant patients have to be transported. This is true even in the case of the Netherlands, where the infrastructure of transport systems is highly developed and distances within the country are small. In the rest of world the interval for time of transport can be greater. This will be true, for example, in countries such as the United States that have emergency services but not dedicated, well developed maternal transport services. More to the point, the inherent problems with transport are in large measure irremediable, even with a huge investment of capital. Professional responsibility is defined prospectively because of the inherent and unpredictable risk to maternal, fetal, and neonatal patients in *any* pregnancy, including uncomplicated pregnancy at the onset of attended labor.

Planned home birth does not meet current standards for patient safety in obstetrics. There is increased relative risk and a persistent absolute risk both of which can be reduced in their incidence by having access to professional standards of perinatal care. To regard these risks as ethically acceptable relegates pregnant and fetal patients who experience adverse events to the category of collateral damage. It is antithetical to professional responsibility to intentionally assign *any* damaged or dead pregnant, fetal, or neonatal patient to this category, even if the number is small.

Patient Satisfaction

The *raison d'etre* for planned home birth is increased patient satisfaction. The RCOG-RCM above-mentioned statement emphasizes that the focus should not be exclusively on the physical safety of planned home birth. It is also important to "acknowledge and encompass issues surrounding emotional and psychological well being. Birth for woman is a rite of passage and a family life event, as well as being the start of a lifelong relationship with her baby."[30]

[xv] Electronic fetal monitoring.

The RCOG-RCM statement is correct to emphasize the biopsychosocial importance of planned home birth. Its biopsychosocial advantages include continuity of an empathetic caregiver, the comfort of home, greater control by the pregnant woman, fewer interventions, and less defensive medicine. These advantages become even more salient if the hospital birth option includes provision of care by non-obstetric physicians or poorly supervised trainees and physicians new to practice, lack of in-house anesthesia or neonatal care, and increased intervention rates driven by defensive medicine or unprofessional self-interest to avoid lengthy attendance at labor.

However, the high rates of transport undercut the *raison d'etre* of planned home birth. Emergency transport, even in its most humane forms, is psychologically and socially disruptive for the pregnant woman whose expectation to deliver at home has suddenly been dashed. The expectation of normal vaginal delivery at home without intervention is put at risk by the higher rates of operative and cesarean deliveries compared to women who labor in the hospital. It is therefore not surprising that a study of Dutch women revealed that the self-reported, persistent levels of frustration including serious psychological problems in transported women compared to those who labored in a hospital persisted even up to 3 years after birth in 17% of all transported women. Most relevant reasons were the necessity of transport from home to the hospital, the inability to cope with pain, the unexpected increased rate of operative deliveries, anxiety about losing the baby during transport, and the dissatisfaction with caregivers.[31] Consequently, it might be argued that planned home birth, often unpredictably and suddenly; fails to fulfill what is promised to pregnant women and therefore expected by them. Unfortunately, none of the other studies has systematically investigated satisfaction/dissatisfaction with planned birth in an intention-to-treat model.

Much can and should be done to create a home-like, psychologically and socially supportive hospital birth to fulfill the legitimate expectations of women for a humane, safe, and undisrupted labor experience with full back-up immediately available. Hospital managers and obstetricians should be aware of the fact that a home-like equipped delivery room can reduce the woman's need for pain relief, even reduce the rate of operative deliveries or episiotomies and increase patient satisfaction. It is also useful if pregnant women and their partners are already familiar with the delivery rooms within a hospital and all possibilities of pain relief. A Cochrane review has stated that a continuous one-to-one care during delivery can reduce per se operative interventions at the second stage of labor.[32] However, the existence of certain shortcomings in connection with hospital birth does not mean that this situation should be addressed by promoting home birth instead. Our focus should be best obstetric care, not second best care, for pregnant, fetal, and neonatal patients.[33]

Planned home birth often does not satisfy its *raison d'etre*, improved patient satisfaction. Professional responsibility requires hospital physicians and midwives to take measures to improve patient satisfaction, by creating home-birthlike environments that are appropriately staffed not only to ensure patient safety, which is the paramount professional responsibility, but also to ensure patient satisfaction. Successful collaborative experience of physicians and midwives, either within the hospital or home-birth centers with access to full back-up, have recently been reported. We fully support and endorse professionally responsible midwifery but reject professionally irresponsible home birth midwifery and advocacy of it.

Cost Effectiveness

Throughout the world fiscal responsibility and accountability have become essential components in clinical practice, organizational leadership, and health policy. It might at first appear that planned home birth offers the potential for cost-savings by avoiding a relatively more expensive hospital admission. The Birthplace in England national cohort study "priced" planned home birth, birth in freestanding midwifery units, "alongside" midwifery units, and obstetric units at, respectively, £1066, 1435, 1461,

and 1631, and concluded that "for multiparous women at low risk of complications, planned home birth is the most cost effective option. For nulliparous low risk women, planned birth at home is likely to be the most cost effective option but associated with an increase in adverse perinatal outcomes."[34]

This is selective and defective cost-effectiveness analysis. A more comprehensive Dutch report calculates a general threefold increase of costs in patients transported during labor, when the costs of the midwife, the transport system, and the obstetricians are included. Even more important, Svensson exposed the failure to include the lifetime costs for support of disabled children which he estimates to be £5 million per handicapped child.[35] In addition, the potential increased cost of professional liability must be considered. A comprehensive and reliable cost-effectiveness analysis would have also to take into account the cost of maintaining an adequate transport system, hospital admission for the pregnant women, admissions to the neonatal intensive care unit, the lifetime costs of supporting the neurologically disabled children who will result from planned home birth, and potentially increased professional liability costs.

Selective cost-effectiveness analysis is not consistent with professional responsibility and may seriously mislead public officials in policy deliberations about permitting and funding planned home birth. If we regard the increased "event" of perinatal or even maternal death – which appears in the British Birthplace study only in an appendix – these calculations become even more problematic, inasmuch as the least expensive patient is a dead patient.

Respect for Women's Rights

There are various considerations that come into play in the given context. On one hand, a pregnant woman has the right to make decisions and control what happens to her body during pregnancy and delivery. On this view, the physician or midwife is bound to acknowledge and implement the patient's preferences. On the other hand, the fetal and neonatal patient cannot be completely subordinated to the woman's rights. On this more clinically appropriate view, the physician or midwife does indeed have an independent obligation, as a matter of professional integrity, to protect pregnant, fetal, and neonatal patients. The physician's or midwife's role is to identify and present medically reasonable alternatives for the management of pregnancy, i.e., clinical management for which there is an evidence base of net clinical benefit.[36]

The patient has the right to select from among the medically reasonable alternatives. If she rejects them all and also remains a patient, then her refusal is not a simple exercise of a negative right to non-interference. Her refusal is more complex, because it is coupled with a positive right to the services of clinicians and the resources of healthcare organizations and society. In all ethical theories positive rights come with limits. In the clinical setting ethically justified limits originate in professional integrity, because professional integrity prohibits provision of clinical management that is not safe.

Insistence on implementing the unconstrained rights of pregnant women to control the birth location is an ethical error and therefore has no place in professional perinatal medicine.

Summary

The ethical analysis of this section supports the conclusion that planned home birth is not consistent with professional integrity because its increased risks are preventable by planned hospital birth. Pregnant women do not have absolute freedom to control the place of assisted birth because they have an ethical obligation to the soon-to-be-birth child to protect its health-related interests. This obligation cannot be fulfilled by planned home birth but can be fulfilled by planned hospital birth. The precautionary principle justifies reducing risks of the vulnerable when the burdens of doing so are minimal. Planned hospital birth protects fetal and neonatal patients from the risks of planned home

birth, from which risks they cannot protect themselves. The burdens on pregnant women of planned hospital birth are minimal. Planned home birth is therefore not compatible with the precautionary principle.

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[14] See reference 7 above.

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