Cancer Association of South Africa (CANSA)

Fact Sheet and Position Statement on Vaccines and Vaccination

Introduction
Most people are aware that vaccines are given to healthy people to help prevent infections, such as measles and chicken pox. These vaccines contain weakened or killed germs like viruses or bacteria to start an immune response in the body. Getting the immune system ready to defend against these germs helps keep people from getting infections.

Some strains of the human papilloma virus (HPV) have been linked to cervical, anal, throat, and some other cancers. Vaccines against HPV may, therefore, help protect against some of these cancers.

People who have chronic (long-term) infections with the hepatitis B virus (HBV) are at higher risk for liver cancer. Getting the vaccine to help prevent HBV infection may lower some people’s risk of getting liver cancer (American Cancer Society).

Several studies have found an increased risk of lung cancer in those who have tuberculosis (TB). A large Chinese study of over 700 000 people found that those who had TB were 11 times more likely to develop lung cancer than those without TB. BCG vaccine helps prevent the incidence of TB (About.Com).

These are traditional vaccines in that they target the viruses and bacteria that can cause certain cancers. They may help protect against some cancers, but they do not target cancer cells directly. These types of vaccines are only useful for cancers known to be caused by infections.

Anti-vaccine Groups
Anti-vaccine groups represent an irrational trend of mistrust of vaccination that is almost as old as the technique itself. These individuals and groups blame vaccines, or their ingredients, e.g. formaldehyde which, in large concentrations can increase the risk for
cancer, for a range of illnesses whose mechanisms are rejected or have not been explained by current scientific research. Some of these maladies can often be childhood illnesses in order to increase the emotive factor of their arguments. The ubiquity of vaccination often makes it an easy target for blame.

Anti-vaccine groups target cancer control organisations who, on the one hand, warn the public against cancer causing chemicals such as formaldehyde, while on the other hand are not seen to warn the public about these same substances that are present in various vaccines albeit in minute concentrations only.

An important question arises: What are the possible health effects, including cancer risk, of some vaccine ingredients like formaldehyde?

The discredited researcher who launched the anti-vaccine movement met with Donald Trump this summer - and found him sympathetic to the cause. Now, with Trump preparing to move into the White House, leaders of the movement are newly energised, hopeful they can undermine decades of public policy promoting childhood vaccinations. At the most basic level, they’re hoping Trump will use his bully pulpit to advance his oft-stated concern - debunked by an extensive body of scientific evidence - that there is a link between vaccines and autism.

Andrew Wakefield is both revered and reviled. To a small group of parents, he’s a hero who won’t back down from his assertion that the measles, mumps and rubella (MMR) vaccine can cause autism.

To most, however, he’s the man who authored a fraudulent study that has been refuted many times and was retracted by the journal that published it, a man whose views carry dangerous consequences for all of us. They will tell you that the former doctor - stripped of his license in 2010 by the United Kingdom’s General Medical Council for ethical violations and failure to disclose potentially competing financial interests - has derailed public confidence in vaccination programs that were safely eradicating serious and highly contagious diseases. (The Huffington Post; Newsweek).

**Anti-Vaccination Arguments Disputed**

- **There's no proof that vaccines don't cause autism.** It's hard to prove a negative. The American Academy of Pediatrics has released a list of more than 40 studies showing no link whatsoever between vaccines and autism.

- **There is a study from England that showed a link between vaccines and autism.** Yes, there was a study published in *The Lancet* in 1998 which pointed to such a link, however, the study was retracted, and the physician-researcher who led it, Dr. Andrew Wakefield, was shown to have falsified the data and, as a result, was stripped of his medical license.

- **There are lots of anecdotes about children developing autism after being vaccinated.** It must be remembered that anecdotes are not scientific proof, and there is no reason to believe that vaccines caused the children to become autistic. As scientists put it succinctly, correlation simply does not imply causation, despite the assumption that many parents make.
It is nobody's business whether my children get vaccinated. Actually, parents who fail to vaccinate their kids may be jeopardising the health of other children who are unable to get the vaccine because they are too young or for any other reasons. When the number of unvaccinated children rises above a certain threshold, so-called ‘herd immunity’ is compromised - and preventable diseases get a toehold in the community.

Vaccines can ‘overload’ a child’s immune system. That is simply not true. From the moment a baby is born, he/she are exposed to all sorts of illness-causing germs and viruses. So most doctors agree that a child's immune system can handle the immune-stimulating antigens in multiple vaccines.

‘Natural’ immunity is better than the immunity that comes from vaccination. So-called ‘natural immunity’ results from the body contracting and successfully battling an infectious illness. Research shows that the immune response of individuals who have been vaccinated against various diseases is just as good as that of people whose immunity comes from an infection. But of course, vaccine-acquired immunity is preferable because it comes without the potentially dangerous infection that could cause much more harm.

(NH Post Science).

Routine Vaccination of Children in South Africa
The average South African child can expect in the region of 28 vaccinations before reaching the age of 12. The first of these vaccinations are routinely given soon after birth.

There will, however, always be some children who are unavoidably unprotected because:

- they cannot be vaccinated for medical reasons
- they are too young for a particular vaccination
- they cannot get to the vaccine services
- the vaccine does not work (although this is rare).

(NHS Choices UK).

The Importance of Immunisation of Children
Everybody wants to do what is best for their children. The importance of car seats, baby gates and other ways to keep children safe is well known. One of the best ways to protect children is to make sure they have all of their vaccinations in line with to the vaccination schedule.

There are at least five (5) important reasons why every child should be vaccinated:

Vaccination can save a child’s life - because of advances in medical science, every child can be protected against more diseases than ever before. Some diseases that once injured or killed thousands of children, have been eliminated completely and others are close to extinction - primarily due to safe and effective vaccines. One example of the great impact that vaccines have had is the elimination of small pox and polio in South Africa. On 24 October 2006 South Africa was officially declared free of the preventable, but incurable, childhood disease of polio. Polio was once a most-feared disease in South Africa, causing
death and paralysis across the country, but today, thanks to vaccination, there are no reports of polio.

**Vaccination is safe and effective** - vaccines are only given to children after a long and careful review by scientists, doctors, and healthcare professionals. Vaccines will involve some discomfort and may cause pain, redness, or tenderness at the site of injection but this is minimal compared to the pain, discomfort, and trauma of the diseases these vaccines prevent. Serious side effects following vaccination, such as severe allergic reaction, are very rare. The disease-prevention benefits of getting vaccines are much greater than the possible side effects for almost all children.

**Vaccination protects others as well** - children in South Africa still get vaccine-preventable diseases. A resurgence of measles and whooping cough (pertussis) occurs every now and then. To help keep children safe, it is important that they get vaccinated. This not only protects the family, but also helps prevent the spread of these diseases to friends and loved ones.

**Vaccination saves time and money** - a child with a vaccine-preventable disease can be denied attendance at schools or child care facilities. Some vaccine-preventable diseases like liver cancer and cervical cancer can result in prolonged disabilities and can take a financial toll because of lost time at work, medical bills or long-term disability care. In contrast, getting vaccinated against these diseases is a good investment and usually can be obtained free.

**Vaccination protects future generations** - vaccines have reduced and, in some cases, eliminated many diseases that killed or severely disabled people just a few generations ago. For example, smallpox vaccination eradicated that disease worldwide. Children do not have to get smallpox shots anymore because the disease no longer exists. By vaccinating children against rubella (German measles), the risk that pregnant women will pass this virus on to their foetus or new born baby has been dramatically decreased, and birth defects associated with that virus is seldom seen in South Africa. If vaccination is continued, parents in the future may be able to trust that some diseases of today will no longer be around to harm their children in the future. (Vaccines.gov).

**Types of Vaccines Available in South Africa**
The following vaccines are available and are (or may be) given to children in South Africa (in alphabetical order):

- BCG – tuberculosis
- Chickenpox
- DTaP – diphtheria, tetanus & whooping cough
- DTaP-IPV/Hib – diphtheria, tetanus, whooping cough, polio, *Haemophilus influenza b*
- DTaP-IPV/Hib/HBV – diphtheria, tetanus, whooping cough, polio, *Haemophilus influenza b & hepatitis B*
- Hepatitis A

[Picture Credit: MMR Vaccine]
Safety of Vaccines

Vaccines are safe, effective and necessary, with huge benefits to children’s health - all through their lives. Vaccines are among the safest tools of modern medicine. The vast majority of side effects from vaccines are minor and temporary, like a sore arm or mild fever. Vaccines are one of the most monitored and studied things in medicine because they are given to healthy children and adults.

Making a new vaccine that is effective and safe takes many years. Vaccines must pass several safety tests before they are ever given to humans. On average, it takes about 10 years of research and development before a vaccine is considered for approval. After a vaccine has been approved for use and made available, its safety is continuously monitored. There are several systems in place world-wide to monitor vaccine safety. Health officials around the world take vaccine safety very seriously.

Some people worry that vaccines can cause health problems, such as autism or sudden infant death syndrome (SIDS). Scientific evidence indicates that vaccines do not cause autism, multiple sclerosis, diabetes, sudden infant death syndrome (SIDS), or other illnesses. These studies are posted on the Institute of Medicine website at: http://books.nap.edu/openbook.php?record_id=13164 (Immunize British Columbia).

Vaccination Against Human Papilloma Virus (HPV) Infection

Two HPV vaccines are now licensed and available in South Africa:

- Cervarix TM will protect against infection with high risk types HPV 16 and 18 (which cause cervical cancer).
- Gardasil ® will protect against infection with high risk types HPV 16 and 18 (which cause cervical cancer) as well as against HPV 6 and 11 (which cause anogenital warts).

The vaccine contains virus proteins that were identified from the most serious types of HPV. It is combined with an inactive substance that stimulates the body to cause a strong immune response. It does not contain any antibiotics or live viruses.

In order to be most effective, the HPV vaccine should be given before a female becomes sexually active. The vaccine should be administered to girls aged 11-12, even as early as age 9. Young women aged 13-18 who have not yet started the vaccine series or who have started but not yet completed the course should be vaccinated. The vaccine will only prevent HPV infection if it is given before a girl has been exposed to the virus (i.e. sexually active).

Studies are currently being done to determine whether the vaccine will prevent HPV infection and genital warts in boys. At this stage the vaccines are not registered for use in males. Furthermore, at present it is not cost effective to vaccinate young boys.

A series of three doses of HPV vaccine within a period of six months should suffice. Current research indicates that a series of only two (2) doses of HPV vaccine provides sufficient protection.

The Gardasil ® HPV vaccine has demonstrated a high success rate in preventing cervical cancer precursors (70%) and genital warts (90%). The Cervarix TM HPV vaccine also claims excellent results in preventing cervical cancer precursors.

We must bear in mind that the vaccine is new, but recent studies have indicated good protection against HPV for five years (which was the duration of the studies). Studies are ongoing to determine if further immunization or a booster dose is necessary.

The vaccines have been tested extensively and all indications are that they are safe. There have been a few side effects reported, the most common being a brief discomfort at the site of the injection.

(South African Society of Obstetricians and Gynaecologists).

**Influenza Vaccination and Cancer Survivors**

Living with cancer increases one's risk for complications from influenza (“flu”). Every person who has cancer or have had cancer in the past (especially children with lymphoma or leukaemia), are at higher risk for complications from the seasonal flu or influenza, including possible hospitalisation and should, therefore, have an influenza vaccination every season.

While one cannot say with certainty that cancer patients and cancer survivors are more likely to get influenza than others, we do know that cancer may increase one's risk for complications from influenza.

Every person with cancer or a history of cancer should receive seasonal vaccinations. People with cancer should, however NOT receive the nasal spray vaccine because their immune system may be weakened. Influenza vaccine is made up of inactivated (killed) viruses, while the nasal spray vaccine is made up of live viruses. The nasal spray vaccine is not approved for use in people with weakened immune systems.
(immunosuppression). Influenza vaccination can be given to people 6 months and older even if they have a weakened immune system or other health conditions.

People who live with, or care for cancer patients and survivors, also should be vaccinated against influenza. Additionally, it is recommended that everyone aged six months and older get an influenza vaccine for the upcoming season.

Many people who are at increased risk for influenza, are also at increased risk for pneumococcal disease. People with cancer or other diseases that compromise their immune system should ask their health care providers if they need vaccination against pneumococcal disease as well.

(American Cancer Society; Cancer Research UK; Centers for Disease Control and Prevention; Medscape).

Vaccine Ingredients
The main ingredient of any vaccine is the disease-causing virus, bacteria or toxin, but a number of other components are needed to make the final vaccine as safe and effective as possible. Chemicals commonly used in the production of vaccines include a suspending fluid (sterile water, saline, or fluids containing protein); preservatives and stabilisers (for example, albumin, phenols, and glycine); and adjuvants or enhancers that help improve the vaccine's effectiveness. Vaccines also may contain very small amounts of the culture material used to grow the virus or bacteria used in the vaccine, such as chicken egg protein. It must be noted that not all of the following ingredients are necessarily present together in every, or all, vaccines.

The following may be present in a particular vaccine.

- **Killed and live vaccines** - vaccines contain ‘killed’ (inactivated) or ‘live’ versions of the disease-causing virus, bacteria or toxin. These are known as the vaccine antigen. Killed vaccines contain previously virulent micro-organisms that have been destroyed with chemicals or heat. These vaccines are also known as inactivated or ‘dead’. Examples of killed vaccines are the flu vaccine, whooping cough vaccine, and polio vaccine. Live vaccines, also called ‘attenuated vaccines’, contain a version of the bacteria or virus that has been weakened (though not destroyed) to make sure it cannot cause disease. Examples of ‘live’ vaccines are the BCG vaccine, MMR vaccine and the children’s nasal spray flu vaccine.

- **Thiomersal (mercury) in vaccines** - Thiomersal is a preservative which contains small amounts of mercury. It is used to prevent the growth of bacteria or fungi in the vaccine. High doses of mercury can be toxic to the brain and other organs. However, no harmful effects have been linked with the level of thiomersal used in such small amounts in vaccines. Although there have been concerns in the past that thiomersal-containing vaccines can cause autism, there is no scientific evidence that this is the case. The World Health Organization (WHO) has stated that there is no risk from thiomersal in vaccines.

- **Adjuvants in vaccines (aluminium)** - adjuvants work to boost the immune response to a vaccine and make it more effective and long-lasting. Using an adjuvant makes it possible to reduce the amount of antigen used in a vaccine and sometimes the number of doses that need to be given. The amount of adjuvant used in a vaccine is very small and has been shown to be safe, although adjuvants in vaccines can be
associated with minor reactions such as a small lump or redness at the injection site. Most killed vaccines contain a very small amount of aluminium-based adjuvant. Although aluminium can be toxic in large quantities, no harmful effects are seen with the level of aluminium used in such small amounts in vaccines.

Humans are constantly in contact with aluminium. It is the most abundant element in the earth's crust and is found in air, food and water. Aluminium is present in the infant's body from birth, and in breast milk and in infant formula. For example, in the first 6 months of life, infants are exposed to approximately 4mg of aluminium in vaccines. In this same time period, they are exposed to approximately 10mg of aluminium in breast milk, 40mg in infant formula, and 120mg in soy formula. Aluminium is present in breast milk and in infant formula in similar amounts as in vaccines. This amount is very small and extremely safe for infants.

In order for aluminium to be harmful, three things have to happen. First, the kidneys must not be working well, or at all, and second, the amount of aluminium entering the body must be very large (hundreds or thousands of times larger than vaccines) and third, it must be constantly given over long periods of time (months or years) so that the body does not have a chance to clear it.

Other Adjuvants - Cervarix, a vaccine to prevent cervical cancer caused by human papillomavirus types 16 and 18, includes AS04 in its formulation. AS04 is a combination of aluminium hydroxide and monophosphoryl lipid A (MPL). MPL is a purified fat-like substance.

In addition, one vaccine for the prevention of H5N1 influenza, commonly referred to as avian influenza or 'bird flu', contains the adjuvant AS03, an oil-in-water emulsion. The AS03 adjuvant is made up of the oily compounds, D,L-alpha-tocopherol (vitamin E) and squalene, and an emulsifier, polysorbate 80, which helps ingredients mix together and keep them from separating, and water containing small amounts of salts.

Gelatine in vaccines - gelatine derived from pigs is used as a stabilising agent in some vaccines. Stabilisers are added to vaccines to help protect them from the effects of heat or freeze-drying and to also help maintain the shelf life of the vaccine. There have been a small number of allergic reactions to vaccines containing gelatine so people with a known allergy to gelatine are advised to consult their doctor before receiving a gelatine-containing vaccine. Religious groups such as Muslims and Jews may be concerned about using vaccines containing gelatine from pigs, however many faith group leaders have stated that the use of gelatine in vaccines is acceptable and does not break any religious rules.

Human serum albumin in vaccines - human serum albumin is a substance from human blood. It is a protein used to stabilise a vaccine and maintain its quality during storage. The serum used in vaccines comes from screened blood donors and the manufacturing process ensures that any risk of transmitting disease is eliminated. Human serum albumin is used as a stabiliser in the MMR vaccine.

Hen’s Eggs in vaccines - flu vaccine is grown on hens’ eggs and is capable of triggering an allergic reaction. Children and adults with egg allergy are, therefore, advised to have an alternative such as an egg-free inactivated flu vaccine. MMR vaccine is grown on cells from chick embryos, which is not the same as hens’ eggs.
and therefore does not trigger an allergic reaction. Children and adults with severe egg allergy can safely receive the MMR vaccine.

- **Formaldehyde in vaccines** - formaldehyde, widely known as an embalming fluid, is a chemical that is also used in the production of killed vaccines. It is used very early in the manufacturing process to kill or 'inactivate' the bacteria, virus or toxin. Once the antigens are inactivated the formaldehyde is diluted out but it is possible trace amounts may remain in the final vaccine. Formaldehyde can be harmful in high concentrations, however, there are no health concerns about the small amounts found in vaccines. Formaldehyde can be found naturally in one's bloodstream. It helps with metabolism and is present at levels far higher than one would be exposed to in vaccines.

Formaldehyde is used to inactivate bacterial products or viruses used in some vaccines. Most formaldehyde is removed from the vaccine before it is packaged. Formaldehyde is naturally produced by the human body because it is required for the body to make DNA and proteins. Humans break down formaldehyde quickly, so it does not build up in the body.

The average quantity of formaldehyde to which a young infant could be exposed at one time may be as high as 0.2 mg. This quantity of formaldehyde is considered to be safe for two reasons:

- First, formaldehyde is essential in human metabolism and is required for the synthesis of DNA and amino acids (the building blocks of protein). Therefore, all humans have detectable quantities of natural formaldehyde in their circulation (about 2.5μg of formaldehyde per ml of blood). Assuming an average weight of a 2-month-old baby of 5kg and an average blood volume of 85 ml per kg, the total quantity of formaldehyde found in an infant’s circulation would be about 1.1mg, a value at least five-fold greater than that to which an infant would be exposed to in vaccines.
- Second, quantities of formaldehyde at least 600 fold greater than that contained in vaccines have been given safely to animals.

- **Antibiotics in vaccines** - antibiotics are added to some vaccines to prevent growth of bacteria during production and storage of the vaccine. They can only be found in tiny amounts in the final vaccine. Antibiotics that are associated with allergic reactions, such as penicillin, generally are not used in vaccines. However, MMR vaccine contains tiny amounts of an antibiotic called neomycin which is capable of triggering an allergic reaction. Anyone known to be allergic to neomycin should consult their doctor before receiving the MMR vaccine.

Examples of antibiotics used during vaccine manufacture include neomycin, polymyxin B, streptomycin and gentamicin. Some antibiotics used in vaccine production are present in the vaccine, either in very small amounts or they are undetectable. For example, antibiotics are used in some production methods for making inactivated influenza virus vaccines. They are used to reduce bacterial growth in eggs during processing steps, because eggs are not sterile products. The antibiotics that are used are reduced to very small or undetectable amounts during subsequent purification steps. The very small amounts of antibiotics contained in vaccines have not been clearly associated with severe allergic reactions.
- **Yeast Proteins in vaccines**: a tiny quantity of yeast protein may remain in Hepatitis B vaccines, though there is no evidence that this can cause allergic reactions.

- **Human Cell-lines in vaccines**: cell culture is the process by which cells derived from living organisms are grown and reproduced in a controlled laboratory environment. In the manufacture of some vaccines, such as the MMR, cultures containing human cell-lines are used to grow a virus. This is because the virus is specific to humans and will not grow in any other medium. The cell-line used in the production of the rubella element of the MMR is grown on a cell culture called WI-38, while the shingles vaccine (Zostavax) is grown on MRC-5. These cultures originated in lung cells taken from two different aborted foetuses in the 1960s (the foetuses were not aborted for this purpose). None of the original cells remain in the culture. It is possible that traces of the cell-culture may remain in the vaccines. Some people have concerns about using a vaccine produced using foetal tissue. The Vatican's position on the matter is that “it is acceptable to use vaccines developed from abortions that were carried out decades ago, because immunizations play a vital role in protecting life by preventing illness and death” (Statement by the Pontifical Academy for Life, 2005).

- **Animal Cell-lines in vaccines**: cell culture is the process by which cells derived from living organisms are grown and reproduced in a controlled laboratory environment. Cultures containing animal cell-lines are used for growing viruses for use in the 5-in-1 vaccines, Pre-school and Teenage boosters, MMR vaccines, Nasal flu vaccine and Rotavirus vaccine. The polio virus element of the 5-in-1 vaccine is grown on Vero cells, that is a cell-line originally derived from the kidney of the African green monkey. The measles and mumps elements of the MMR are grown on a culture derived from cells taken from a chick embryo. These facts are sometimes distorted by anti-vaccine campaigners, in order to suggest that vaccines are a kind of witch’s potion, or that there is a risk that animal disease may be transmitted by vaccines.

- **Monosodium glutamate in vaccines**: is used as a stabiliser in a few vaccines to help the vaccine remain unchanged when the vaccine is exposed to heat, light, acidity, or humidity.

- **2-Phenoxy-ethanol in vaccines**: is also used as a stabiliser in a few vaccines to help the vaccine remain unchanged when the vaccine is exposed to heat, light, acidity, or humidity.

- **Sugars, amino acids, and proteins in vaccines**: these substances may be added as stabilisers. They help protect the vaccine from adverse conditions such as the freeze-drying process, for those vaccines that are freeze dried. Stabilisers added to vaccines include: sugars such as sucrose and lactose, amino acids such as glycine or the monosodium salt of glutamic acid and proteins such as human serum albumin or gelatine. Sugars, amino acids and proteins are not unique to vaccines and are encountered in everyday life in the diet and are components that are in the body naturally.

- **Suspending fluid in vaccines**: this is usually sterile water, saline, or fluids containing protein (NHS Choices UK; Oxford Vaccine Group; Centers for Disease Control and Prevention; Immunize British Columbia; The Vaccine Times; Children’s Hospital of Philadelphia; Harpocrates Speaks; About.Com; IARC Monographs Vol 88; Science-based Medicine; US Food and Drug Administration).
CANSA’s Position

CANSA believes:

- It is the responsibility of parents and guardians to do everything possible to make sure their children are healthy and protected from preventable diseases including certain cancers and vaccination is the best way to ensure that.

- Vaccination protects children from serious illnesses and complications of vaccine-preventable diseases which can result in amputation of an arm or leg, paralysis of limbs, hearing loss, convulsions, brain damage, and death.

- Vaccine-preventable diseases, such as measles, mumps and whooping cough, are still a threat and can result in hospitalisation and death, therefore, vaccination is the proper way to protect all children.

- Although vaccination has already led to a dramatic decline in the number of South African cases of various infectious diseases, some of these diseases are still common in other countries and may be brought to South Africa by international travellers. Children should, therefore, continue to be vaccinated against these diseases to protect them from the diseases that may be brought into South Africa by international travellers.

- Outbreaks of preventable diseases will occur when children are not continued to be vaccinated.

- Even though some components contained in vaccines may be harmful or dangerous to humans if they are exposed to it in large quantities or volumes, the minute volumes of these substances that may be present in vaccines pose no danger to human health.

- Vaccination is safe and effective because all vaccines undergo long and careful review by scientists, doctors and other health professionals to make sure they are safe.

- CANSA, therefore, supports vaccination by means of vaccines that have been approved and registered by the Medicines Control Council (National Department of Health).
Medical Disclaimer
This Fact Sheet and Position Statement is intended to provide general information only and, as such, should not be considered as a substitute for advice, medically or otherwise, covering any specific situation. Users should seek appropriate advice before taking or refraining from taking any action in reliance on any information contained in this Fact Sheet and Position Statement. So far as permissible by law, the Cancer Association of South Africa (CANSA) does not accept any liability to any person (or his/her dependants/estate/heirs) relating to the use of any information contained in this Fact Sheet and Position Statement.

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Ban Water!
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