

To
Dr. G. N. Singh
Drugs Controller General of India
Central drugs standard control organization,
Directorate general of health services
Ministry of Health and Family Welfare
Government of India
FDA Bhavan, ITO, Kotla Road,
New Delhi - 110002.

5th February, 2015.

Sub : *Request for revision in the present format in the Drugs and Cosmetics (Amendment) Bill, 2015, in connection with the inclusion of "Stem Cells as a new drug." (Clause 7 (x) (iv)*

Respected Sir,

We are writing to you in connection with the Drugs and Cosmetics (Amendment) Bill, 2015, Clause 7(X)(IV), in which Stem Cells have been included under the category of new drugs.

We wish to point out the following :-

- 1) Stem Cell may broadly be divided into two types :-
"Autologous" (taken from the same patient) and "Allogenic" (derived from other than the patient). These are two very different types of cells. Autologous Stem Cell Therapy has been popular for various hematological for the last 3 decades and for other incurable conditions over the last 5 to 10 years. Whereas allogenic Stem cells are manufactured by companies, it may be appropriate to consider them in the same regulations as a new drug. However, Autologous stem cells are not a product since they are not manufactured and hence considering them in the same category as a new drug would not be appropriate. This would be similar to putting home made orange juice in the same category as Fanta/Miranda.

The US FDA also makes this distinction since in US FDA Article 1271.15v it states that "You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure."

We, therefore, suggest that either stem cells should be removed from the category of new drugs but if it has to be kept then, it should be kept "Allogenic stem cells". By doing this, stem cells that are being manufactured and sold by companies and are therefore a product will come under the category of new drug whereas autologous stem cells which are being used by individual doctors will not be included in this category.

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- 2) The Japanese Parliament has passed a law in November 2014 that offers fast track approvals for Stem Cell Therapies. Under this new law, Stem Cells will no more be considered as drugs and will not have to undergo the three phases of costly and cumbersome clinical trials to get approval. We, therefore, request that the new Japanese law be studied and suitably be adapted to Indian conditions.
- 3) India has developed a leadership particularly with autologous cell therapy and there are many scientific publications in International medical journals from India that have documented this work. The new proposed law will destroy India's leadership in this field.
- 4) If the proposed law is implemented, then only big corporates with large amounts of money will be able to do the three phase clinical trials that need to be done for a new drug. This will make Stem Cell Therapy very expensive and non-affordable to the poor and middle-class of India. Public hospitals as AIIMS - New Delhi, PGI - Chandigarh, LTMG Hosp. - Mumbai, that offer can offer autologous stem cell therapy almost free or at subsidized cost and small private hospitals that offer it at low cost will not be able to do so anymore. Therefore the new law will deprive the poor and middle class of India with the much needed new treatment form.
- 5) With regard to Autologous Stem Cell Therapy when viewed from the point of view of the three parameters mentioned in the DCGI Order dated 5th September 2014, the following can be stated :-
 - (i) **Assessment of risk versus Benefit to the Patient :-** Autologous Stem Cells are absolutely safe and there is no risk whatsoever and their use over the last several years in clinical practice, clinical studies as well as scientific publication. The benefit to the patients is huge and in many diseases such as muscular dystrophy and motor neuron disease it can be life-saving.
 - (ii) **Innovation vis-à-vis existing therapeutic option :-** Autologous Stem Cell Therapy is a definitive medical innovation and there are several publication in India that have shown its innovation results. Many of the diseases that can be treated by these have no other therapeutic options.
 - (iii) **Unmet Medical need in the country :-** There are many incurable conditions such as autism, cerebral palsy, mental retardation, muscular dystrophy in children and Brain Stroke, spinal cord injury, motor neuron disease, dementia in adults that have a major unmet medical need, since currently there are no available medical or surgical therapeutic options for these conditions. The potential beneficiaries in our country would be in lakhs.
- 6) Please also note that the Prime Minister of our country, Shri Narendra Modi has shown special interest in the field of Stem Cell Therapy. This is evident by the fact :-
 - (a) When he visited Japan, he visited the Stem Cell Institute in Kyoto and met with Prof. Yamanaka.
 - (b) In the address by President of India to the joint session of the Lok Sabha at the central hall of parliament where the President shared your governments agenda for the country in paragraph 38 it states "My government will build world class research centers in the fields of nanotechnology, material sciences, thorium technology, brain research, stem cells".

From this it is clearly evident that the top leadership of the country would like to see Stem Cell Therapy promoted and not destroyed as will happen if the proposed bill is passed in its present form.

We, therefore conclude and request the following :-

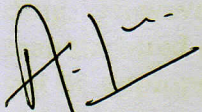
That (a) keeping in mind our national interest, the interest of our patient's health and pioneering work already done by our country's medical practitioners and (b) in accordance with the US FDA Article 1271.15v and the new Japanese Legislations on Stem Cell Therapy, either stem cell therapy should not be included in the category of new drug or if it has to be included then it should be included as "Allogenic Stem Cells". Alternatively, it could be mentioned that minimally manipulated Autologous Stem Cells will not be considered as a new drug. This will simultaneously ensure that stem cells that are been manufactured and are marketed as products (allogenic stem cells) are kept under strict regulations whereas autologous stem cells which are safe, have a published track record of efficacy in several incurable conditions and which are not a product are available for patient's benefit.

Please find attached a letter which we have written to Prime Minister, Shri Narendra Modi as well as emails sent to you earlier alongwith other documentary evidence of what we have mentioned in this letter.

We look forward to your support in protecting Stem Cell Therapy in India.

Thanking you,

Yours faithfully,



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Date:
22/12/14

To
Shri Narendra Modi
Prime Minister of India

Subject: *Request for your intervention to make the proposed guidelines/ regulations in the field of Stem cell therapy more patient and doctor friendly and in our national interests.*

Respected Sir,

{I} The Issue :- Stem Cell therapy in India

Stem Cell Therapy is new form of treatment using which many medical conditions that were earlier considered incurable or untreatable can now be treated.

India (along with China and Japan) is a leader in this field since Indian doctors have played a pioneering and leadership role in the field of stem cell therapy. Hundreds of patients are now coming to India from all over the world for this treatment. There are many scientific publications in International medical journals on the clinical aspects of stem cell therapy from India.

{II} The Problem:- New proposed guidelines / regulations that will be harmful to this new field

The Indian Council of Medical Research(ICMR) , the Drug Controller General of India (DCGI) and Central Drugs Standard Control Organization (CDSCO) have recently proposed and are starting to implement a new set of guidelines, which though well intentioned, have been prepared without taking into account the perspective of patients suffering from incurable diseases and the doctors practicing this therapy. This is the way western countries (who are unhappy with the fact that patients from their countries are coming to India for this therapy) look at this issue and so inadvertently these guidelines have developed a anti stem cell therapy bias.

A major flaw in these new regulations is that a proper distinction has not been made between Autologous stem cells (taken from the patients own body and put back in the same patient by doctors) and Allogenic (taken from other patients and manufactured by companies). Autologous stem cell therapy is 100 % safe, beneficially in many incurable illnesses, does not require major and expensive infrastructure so can be given by individual doctors in smaller setups and India has a leadership in this field. The consequence of the new regulations will be that public and government hospitals who can offer autologous stem cell therapy almost free of cost to the poor patients of the country will not be able to do so and only some corporates will benefit who manufacture these and have the financial capacity of implement the regulations. AIIMS (New Delhi) , PGI (Chandigarh) , Lokmanya Tilak Municipal General Hospital (Mumbai) etc all offer autologous stem cell therapy free of cost to poor patients and their work will get restricted with the new policy.

Also Indian doctors who have pioneered this treatment and patients who have benefited from it have not been consulted before drafting these guidelines. The following will be the consequences of this new policy :-

- (1) This we believe will be very harmful to the growth of the entire field in India.
- (2) It will also be against the interests of both the patients in our country as well as the doctors who have worked on these treatments.
- (3) Poor patients needing this treatment will not be able to avail of the same.
- (4) It is also against three of your publicly stated policies :- (a) To promote "Made in India" and (b) To end one old and obsolete law everyday and (c) To have "Less government and more governance."

This is completely opposite to what the Government of Japan has done. Just last month they passed a new law that has made it much easier for Japanese doctors to do stem cell therapy in their country.

{III} Why We are writing to you :-

We are writing to you since (a) It was under your leadership that Gujarat was the first state in the country to set up a 90 Crore Stem cell therapy center in the Civil hospital in Surat, (b) Also in your recent visit to Japan you visited The Stem cell Institute and met with Professor Yamanaka, & (c) In the address by President of India to the joint session of the Lok Sabha at the central hall of parliament where the President shared your governments agenda for the country in paragraph 38 it states "My government will build world class research centers in the fields of nanotechnology, material sciences, thorium technology, brain research, stem cells". So we believe that you understand and appreciate the importance of this new field to the people of the country.

We believe that must be oversight and regulations but the regulations should not be such that they kill the field itself and are harmful to our countries interests. The thinking and commercial interests of western countries should not influence our National policies. Stem cell therapy is something which is very much presently being "Made in India" but the new regulations will destroy that. In view of all this we believe you will see this issue in the larger national interests and then direct the regulatory bodies to also do the same.

{IV} What is the solution to this problem:-

We are requesting the following from you Sir :-

- [1] That you grant us a meeting in which we can present to you all the facts.
- [2] That the Ministry of Health be requested to ask the DCGI / CDSO/ ICMR to give us a hearing so that we can present the facts to them from the patient and doctors viewpoint too.

[3] That autologous stem cell therapy which will benefit lakhs of poor patients and which can be easily given in government hospitals and smaller private hospitals be freed up from the strict new regulations.

[4] That the regulatory bodies have "Less government and more governance" and in accordance with that whilst always keeping public safety in mind, let the medical doctors and stem cell experts decide what medical indications to treat with stem cell therapy based on their experience, track record, scientific publications etc.

[5] That those formulating the new regulations in this field study the new Japanese law and incorporate some of the basic principles of their legislation and create a more progressive set of regulations for India.

We eagerly look forward to meeting with you and sharing our thoughts, concerns and possible solutions.

Thanking You.

With Warm Regards

Your sincerely


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