



# Drug Information Bulletin

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*Bengal Branch*

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## Editorial

Nobel Prize in Physiology or Medicine for the year 2016 was awarded to Dr. Yoshinori Ohsumi of Tokyo Institute of Technology, Tokyo, Japan for his discoveries of mechanisms for autophagy. Dr. Ohsumi discovered and elucidated mechanisms of a fundamental process for degrading and recycling cellular components – autophagy.



The word autophagy originates from the Greek words auto-, meaning "self", and phagein, meaning "to eat". Thus, autophagy denotes "self eating". This concept emerged during the 1960's, when researchers first observed that the cell could destroy its own contents by enclosing it in membranes, forming sack-like vesicles that were transported to a recycling compartment, called the lysosome, for degradation. The mechanism of autophagy was not clear until, in a series of brilliant experiments in the early 1990's, Yoshinori Ohsumi used baker's yeast to identify genes essential for autophagy. Dr. Yoshinori then went on to elucidate the underlying mechanisms for autophagy in yeast and showed that similar sophisticated machinery is used in our cells. Ohsumi's discoveries led to a paradigm shift in understanding of how the cell recycles its content. His discoveries opened the pathway to understanding the fundamental importance of autophagy in many physiological processes, such as in the adaptation to starvation or response to infection. Mutations in autophagy genes can cause disease, and the autophagic process is involved in several conditions including cancer and neurological disease. This discovery will be very much useful in future for developing drugs of several diseases like Cancer.

**Dr. Subhash C. Mandal**

**Editor**

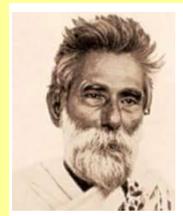
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## Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2016 invited

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3<sup>rd</sup> week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.



IPA, Bengal Branch Council select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy.

Any member of IPA can recommend name of the person with their detailed Bio-data & Two Page summary of the Bio data for 2016 award, which may be sent by **17<sup>th</sup> October 2016** to:

### **The Hony. Secretary,**

Indian Pharmaceutical Association, Bengal Branch,  
22 B Panchanontola Road,  
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### **N.B.: Biodata should include the following points-**

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
  - a. Whether member of IPA? If yes, how many years?
  - b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
  - a. President/Vice President / Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
  - b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.

## Doctors are the Third Leading Cause of Death in the US, Killing 225,000 People Every Year

As per an article published in JAMA which is the most widely circulated medical periodical in the world. The author is Dr. Barbara Starfield of the Johns Hopkins School of Hygiene and Public Health and she describes how the US health care system may contribute to poor health.

### ALL THESE ARE DEATHS PER YEAR:

- **12,000 -- unnecessary surgery**
- **7,000 -- medication errors in hospitals**
- **20,000 -- other errors in hospitals**
- **80,000 -- infections in hospitals**
- **106,000 -- non-error, negative effects of drugs**

**These total to 225,000 deaths per year from iatrogenic causes!!**

What does the word iatrogenic mean? This term is defined as induced in a patient by a physician's activity, manner, or therapy. Used especially of a complication of treatment.

Dr. Starfield offers several warnings in interpreting these numbers:

- First, most of the data are derived from studies in hospitalized patients.
- Second, these estimates are for deaths only and do not include negative effects that are associated with disability or discomfort.
- Third, the estimates of death due to error are lower than those in the IOM report.

If the higher estimates are used, the deaths due to iatrogenic causes would range from 230,000 to 284,000. In any case, 225,000 deaths per year constitutes the third leading cause of death in the United States, after deaths from heart disease and cancer. Even if these figures are overestimated, there is a wide margin between these numbers of deaths and the next leading cause of death (cerebrovascular disease).

Another analysis concluded that between 4% and 18% of consecutive patients experience negative effects in outpatient settings, with:

- 116 million extra physician visits
- 77 million extra prescriptions
- 17 million emergency department visits
- 8 million hospitalizations

- 3 million long-term admissions
- 199,000 additional deaths
- \$77 billion in extra costs

The high cost of the health care system is considered to be a deficit, but seems to be tolerated under the assumption that better health results from more expensive care.

However, evidence from a few studies indicates that as many as 20% to 30% of patients receive inappropriate care.

An estimated 44,000 to 98,000 among them die each year as a result of medical errors.

This might be tolerated if it resulted in better health, but does it? Of 13 countries in a recent comparison, the United States ranks an average of 12th (second from the bottom) for 16 available health indicators. More specifically, the ranking of the US on several indicators was:

- 13th (last) for low-birth-weight percentages
- 13th for neonatal mortality and infant mortality overall
- 11th for postneonatal mortality
- 13th for years of potential life lost (excluding external causes)
- 11th for life expectancy at 1 year for females, 12th for males
- 10th for life expectancy at 15 years for females, 12th for males
- 10th for life expectancy at 40 years for females, 9th for males
- 7th for life expectancy at 65 years for females, 7th for males
- 3rd for life expectancy at 80 years for females, 3rd for males
- 10th for age-adjusted mortality

The poor performance of the US was recently confirmed by a World Health Organization study, which used different data and ranked the United States as 15th among 25 industrialized countries.

There is a perception that the American public "behaves badly" by smoking, drinking, and perpetrating violence." However the data does not support this assertion.

- The proportion of females who smoke ranges from 14% in Japan to 41% in Denmark; in the United States, it is 24%

(fifth best). For males, the range is from 26% in Sweden to 61% in Japan; it is 28% in the United States (third best).

- The US ranks fifth best for alcoholic beverage consumption.
- The US has relatively low consumption of animal fats (fifth lowest in men aged 55-64 years in 20 industrialized countries) and the third lowest mean cholesterol concentrations among men aged 50 to 70 years among 13 industrialized countries.

These estimates of death due to error are lower than those in a recent Institutes of Medicine report, and if the higher estimates are used, the deaths due to iatrogenic causes would range from 230,000 to 284,000.

Even at the lower estimate of 225,000 deaths per year, this constitutes the third leading cause of death in the US, following heart disease and cancer.

Lack of technology is certainly not a contributing factor to the US's low ranking.

- Among 29 countries, the United States is second only to Japan in the availability of magnetic resonance imaging units and computed tomography scanners per million population. 17
- Japan, however, ranks highest on health, whereas the US ranks among the lowest.
- It is possible that the high use of technology in Japan is limited to diagnostic technology not matched by high rates of treatment, whereas in the US, high use of diagnostic technology may be linked to more treatment.
- Supporting this possibility are data showing that the number of employees per bed (full-time equivalents) in the United States is highest among the countries ranked, whereas they are very low in Japan, far lower than can be accounted for by the common practice of having family members rather than

- hospital staff provide the amenities of hospital care.

Ref. Journal American Medical Association July 26, 2000; 284 (4):483-5

### **FDA issues new recommendations for proving bioequivalence of generic drugs**

The FDA has issued its third bioequivalence guidance for generic-drug-makers, including 34 new and 33 revised drug-specific recommendations that describe the agency's standards for development of generic drugs that are therapeutically equivalent to reference-listed drugs. The agency is seeking feedback before finalizing the draft guidance.

Ref. [Regulatory Focus](#)

### **OTC drug maker in Brazil warned by US FDA**

Brazilian over-the-counter drugmaker Mappel received a US FDA warning letter citing four violations involving specification conformance, documentation, production and process control. The company said it did not realize that certain OTC products for the US market were FDA regulated and would file with the agency if it resumes production for the US market.

Ref. [Regulatory Focus](#)

### **Additional results reported for trials of psoriasis drug**

Sun Pharma released additional results from two late-stage studies of psoriasis drug tildrakizumab, noting that 77% of patients in the trial experienced 75% skin clearance with three injections of the drug after 28 weeks. The drug's safety profile remained good, with adverse effects in only 1% to 3% of patients.

Ref. [The Economic Times](#)

## **National Pharmacy Week Celebration**

20-27 November 2016

Organizer: IPA-Bengal Branch

Inauguration on 20.11.2016

Venue: Central Glass & Ceramic Research Institutes, Jadavpur (opposite Jadavpur Police Station)

## **DISCLAIMER:**

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