The mantra that has been repeated from middle school science class to university is “All living things are made up of cells.” Cell biology was a forefather to genetics. In 1839, Jakob and Swan developed “cell theory,” in which the mantra has its roots.

1.1 The Prokaryotic Cell

To understand genetics, one must first understand the cell. Cells are classified as prokaryotic or eukaryotic, depending on whether they have a nucleus. Bacteria are the most commonly cited examples of prokaryotic cells. It is generally believed that it was that prokaryote that eventually formed from the primordial soup of our oceans.

At its simplest form, a prokaryotic cell contains (1) a membrane that forms a three-dimensional boundary; (2) the cytoplasm, which
contains the molecular structures needed for a cell to survive; and
(3) the instructions necessary to reproduce.

Without reproduction, all life would cease to exist within one
generation. Thus, life (in a biological sense) is the ability to main-
tain and reproduce. A bacterium reproduces by making an exact
copy of itself. The DNA (which is discussed later in much more
detail) is the architectural plan for making this copy. Using the
machinery of the cell, the DNA is copied, creating a cell with two
identical copies of DNA. The bacterium undergoes a process by
which it segregates its internal machinery such that there is a
line of demarcation where each side contains machinery (more are
created later). The bacterium then simply pinches off at this line—
creating two bacteria where there was once one.¹

One bacterium becomes two bacteria. Two bacteria become
four. Four bacteria become eight, and so on. This is exponential
growth. The standard model for exponential growth is:

\[ N(t) = 2^t N(0) \]

Where:
- \( N(t) \) is the number of bacteria at time \( t \), and
- \( N(0) \) is the number of initial bacteria

For example, if there were 1,000 initial bacteria, and it takes one
day for a bacterium to divide, then at the end of a week there would
be 128,000 bacteria! Each one would be a clone of the original.²

Why is this important from a legal perspective? Let’s assume
a company produces an energy drink. The company determines
that there has been a contamination in the factory line and esti-
mates 1,000 bacteria that could potentially cause blindness were
introduced into each bottle. It is also determined that it would take
approximately 10 billion (10,000,000 times the initial population
of 1,000) bacteria to cause this harm—again, assuming a doubling
rate of one day. Because the colony doubles every day, we need to
find a number \( t \) such that:

\[ 10,000,000 = 2^t \]

Solving:

\[ \log 10,000,000 = \log 2^t = t \log 2 \]
Therefore:

\[ t = \frac{\log 10,000,000}{\log 2} \]

\[ \frac{7}{0.30} = 23.3 \text{ days} \]

Therefore, in approximately 23 days, the energy drink will become toxic. The difference in exposure of the company to civil damages or even criminal judgments could be mitigated by how quickly the company acts. If the company could recall all units within fourteen days, then (from a simplistic view) there would be no harm, or at least no blindness. However, if the company failed to act swiftly, the damages could be much more severe.

1.2 The Eukaryotic Cell

Eukaryotic cells are much more complicated, and much more genetically interesting. Although there are many differences between the eukaryotic and prokaryotic cells, the most relevant difference is that a eukaryotic cell has a nucleus.

The nucleus is a three-dimensional storage area in a cell that holds its genetic material. DNA is copied within the nucleus, as opposed to the cytoplasm of the prokaryotic cell. This function is not the exclusive function of the nucleus, for it plays a role in cell division through its “management” of cellular activity.

Multicellular organisms (such as humans) contain many types of eukaryotic cells. While many think of the “big five” types of cells—muscle, nerve, blood, brain, and skin—there are actually close to 100 or more types of cells in the human body.

1.3 Blood Cells

Blood cells are not like wine, coming in either red or white! In fact, blood contains lymphocytes, monocytes, neutrophils, platelets, and many other types of cells. Red blood cells are the simplest to understand. They transport oxygen from the lungs to every part of the body. Because red blood cells bind oxygen with a molecule called hemoglobin, in many organisms, including humans, they have no nucleus. Thus, they have no DNA. These cells are made in the bone marrow, and thus they do not replicate themselves.
White blood cells do have DNA, and they also play a crucial role in sustaining life. Each day we are bombarded with millions of “germs.” Fighting off these germs is the purpose of the immune system.

In an example, Client missed her deposition because of a severe strep throat. She is intolerant to antibiotics and thus needs to rely on her immune system to fight the infection. Streptococcus bacteria are the cause of a strep infection. The immune system must attack and remove the bacteria in order to end the infection. A Streptococcus bacterium has molecules, antigens, that have a unique shape that is particular to that specific group of bacteria. The immune system enlists T-cells and B-cells (white blood cells) to initiate an attack. These “reconnaissance” cells work together to produce antibodies that attach to the antigens. The antibodies will encapsulate the bacteria. Finally, the infantry is sent in to make the kill. Cells such as phagocytes patrol the body for any bacteria with attached antibodies. After finding the bacterial cells, the phagocytes engulf them and ultimately destroy them.

To combat the millions of germs we encounter daily, hand sanitizer stations have become ubiquitous. Many people even carry small bottles of hand sanitizer with them in the event there is a pressing need to combat a germ. This is not a new revelation in health care. Many baby boomers will remember at least one parental “assault” with a “Wash’n Dri” packet. Now, those first-line-of-defense cloths are relegated to restaurants offering BBQ ribs.

Hand sanitizers have already become of interest to regulatory agencies, because some products claim to prevent MRSA infections. MRSA (pronounced “mer-sa”), methicillin-resistant Staphylococcus aureus, infections are extremely difficult to cure due to their low response rate to antibiotics. The infections are also referred to as “hospital infection” because of the susceptible weakened immune systems of patients found in hospitals.

In April 2011, warning letters from the U.S. Food and Drug Administration (FDA) were issued to four companies that produce hand sanitizers (or similar products). The warning letters were provoked by company statements that some sanitizers kill “99.9% of MRSA.” Deborah Autor, then compliance director of FDA’s Center for Drug Evaluation and Research (CDER), announced that the “FDA has not approved any products claiming to prevent infection from MRSA, E. coli, Salmonella, and the H1N1 flu.” Autor, referring to over-the-counter products, noted that such claims are, in fact, illegal.
Thus, even washing one’s hands may be falling under federal regulations!

Biology, however, through white blood cells, has provided a mechanism to fight off infections. The field of immunology focuses on this. From a legal perspective, a quick search of cases containing the search terms “immunology” and “tort” yields numerous results, as of the drafting of this manuscript. In a silicon breast implant case, *Hall v. Baxter Healthcare Corp.*, there was much expert testimony on whether leakage of implants could have immunological consequences. Such might include enhanced responses of the immune system, triggering and exacerbating and existing immune-mediated conditions. Though many experts testified to immunological consequences, the court excluded the evidence under *Daubert*.\(^5\) This was twenty years ago.

### 1.4 Chromosomal DNA Packing

The nucleus of a eukaryotic cell contains its DNA, and the DNA must be packed in such a way as to fit within it. While the numbers vary a bit, each human cell contains about six feet of DNA. Using histones and non-histone proteins and wrapped DNA, nucleosomes are formed. In humans, this packing can compact DNA 10,000-fold! See Figure 1.1.\(^6\)

![Nucleosome Diagram](image-url)

**FIGURE 1.1** Supercoiled Structure of Circular DNA Molecules with Low Writhe
Because of the limited space in the cell, the DNA requires constant packing and unpacking whenever it needs to be copied or needs to build cellular structures.

Having been presented with some basic principles of cells, the basis of life, one can now look at their production.

Endnotes


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