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## Scientific Paper

### **BackGround Essay:**

Evaluating the Strengths and Weakness In animal models in Biomedical Research and Alternatives

For a long time, animal models have been a big part of biomedical research, because they let scientists study how a disease or treatment affects an entire living system. With the FDA now introducing the idea of reducing animal testing, it raises whether animal models are still the best option or if newer methods can replace them while also producing the same results. Although animal studies have assisted researchers in making important medical discoveries, they also have ethical limitations that make their usefulness more complicated.

One strength of animal models is that they allow researchers to see how different body systems interact during a disease or after a drug is given. For example, a scientist can look at immune responses, metabolic changes, and organ function at the same time, which is something that can be created in cell cultures. Animal testing is also looked at as a key step before human clinical trails because it helps identify toxic side effects and estimate safe dosage levels. This reduces the chances of exposing human participants to dangerous compounds early in drug testing. Another reason animals are used is because certain species, especially mice, share many goals with humans. This makes them useful for studying diseases like cancer or diabetes and testing potential treatments. In addition, animal experiments allow researchers to control factors such as

diet, environment, and genetics, which helps make results more consistent and easier to analyze.

At the same time, there are several limitations that make animal models less reliable than some scientists believe they are. One issue that stood out to me while reading the literature is how often the giving results in animal testing fail to match or mimics what happens in human trials. Although during the process of treatment on mice can give a positive successful outcome, it can also show little effect in people, because of differences in metabolism and immune system function (Van Norman, 2016). This makes it harder to solely depend on animal data when trying to predict real clinical outcomes when it comes to testing a new treatment on humans. There are also ethical concerns, since many experiments can cause stress or harm to the animals, which is one of the reasons researchers are being pushed to look for alternatives. Another problem researchers have encountered is the cost and time required to maintain animal facilities and run long-term studies. If you compare this to much newer and up-to-date laboratories, it will show that this can result in slower research time. In addition, laboratory animals are usually bred to be genetically similar, which helps with experimental control but can also cause a negative effect when including the diversity amongst humans. Because of this, results may not apply as broadly as researchers hope.

Newer technologies are being developed that may reduce the need for animal testing in some areas of research. One example is the use of organelles and organ-on-a-chip systems, which are re-created from human cells and are designed to ionic the structure and function of real tissues. These models allow researchers to study how human cells

respond to drugs in a more direct way, which may improve how well results translate to clinical outcomes (Low et al., 2021). Another advantage of these systems is that they avoid many of the ethical concerns associated with animal testing. They can also be faster and less expensive to maintain compared to long term animal studies. However, while these technologies are promising, they still cannot fully respect the complexity of an entire living organism. Processes such as interactions between multiple organ systems, long term disease progression, and whole body metabolism are difficult to replicate in vitro. Because of this, completely replacing animal models at this time does not seem realistic.

Animal models have contributed significantly to biomedical research, especially in understanding disease mechanisms and improving drug safety. At the same time, the limitations related to translation, cost, time, and ethical concerns show why researchers and regulatory agencies are looking for alternative approaches. Based on the current evidence, a combined strategy that uses both animal models and newer human based technologies may provide the most accurate and efficient path forward. This approach allows scientists to continue benefiting from the strengths of animal research while also improving the relevance of results to human health.

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### **New Approach Methodologies:**

Animal testing has been a major part of scientific research since the beginning of drug development in the medical field. Even though animal models have helped researchers learn a lot, they do not always show the effectiveness of how the human body will actually respond to a drug. Because of this, scientists have been working on new approach methodologies, also known as NAM's, that can test drugs in ways that are more human-based and more accurate. Two of the most important examples are 3D organoids and microfluidic organs-on-chips, especially when they are made from human induced pluripotent stem cells, also known as iPSCs. These methods are becoming more valuable because they can create testing systems that act more like real human tissues rather than animal models.

One of the biggest problems with animal testing is that animals and humans are biological different. A drug might look safe or effective in mice or rats, but that does not mean it will work the same way in people. Human organs, metabolism, and immune responses are much more specific than what animal models can fully show.

"Researchers are starting to move away from relying so heavily on animal experiments because they often do not predict human outcomes as well as scientists need them to" (Kwon, 2026). This reason is a major reason why newer human based models are becoming more important in biomedical research.

A big part of this change comes from the use of iPSCs. These are adult human cells that scientists can reprogram, so they behave like stem cells. Once that happens, they are able to turn into many different types of cells in the body, such as liver cells and kidney cells. This is useful for scientists and researchers because it gives both a way to test drugs on actual human derived cells instead of spending only on animal tissues. In Rowe and Daley (2019) research they both explain that iPSCs have become especially valuable in disease modeling and drug discovery because they make it possible to study human cell behavior more directly. They also help support the idea of personalized medicine, since cells can sometimes come from individual patients. One important use of iPSCs is the development of 3D organoids. Organoids are small, lab-grown tissue models that are designed to act like miniature versions of human organs. They are much more realistic than a flat 2D cell cultures that have been a custom use of research testing in labs for years because they have a three-dimensional structure that better reflects how cells are arranged in the body. This matters because cells behave differently depending on the environment around them. For example, liver organoids can be used to study how drugs are broken down and whether they cause toxicity. In Shinozawa et al. (2021) research showed that human stem cell derived liver organoids could be used to detect drug induced liver injury, which is one of the most

common reasons drugs fail during development. This makes organoids a strong tool for improving safety testing before drugs ever reach human patients.

Another major advancement is the use of organs-on-chips. These are small devices that combine living human cells with tiny channels that allow fluid to move through them, which helps recreate conditions that are closer to what happens inside the body. This is important because cells do not naturally live in still environments such as a Petri dish. Instead, they are constantly exposed to flow, pressure, and movement. Organs-on-chips can copy some of those conditions. For example, a lung-on-a-chip can imitate breathing motions, and a gut-on-a-chip can mimic movement and fluid flow in the digestive system. According to Ingber (2022), organ chips can model human organ functions, disease, and drug responses in ways that are often more realistic than older laboratory systems or many animal-based models. This gives researchers a better chance of understanding how drugs might behave in a real human tissue.

Together, organoids and organs-on-chips offer several clear advantages over animal testing. First, they are based on human cells, which automatically makes them more relevant to human biology. Second, they can be designed to focus on specific tissues or organs, which is useful for studying side effects and toxicity. Third, they may reduce the need for animal experimentation, which also raises important ethical benefits. These methods are especially useful in toxicology because they can help researchers identify harmful drug effects earlier in the testing process. In that way, they are helping improve both the science and the ethics of drug development.

At the same time, these methods are not perfect. Even though organoids and organ chips are much more advanced than older lab models, they still cannot completely copy

the complexity of the full human body. The body depends on communication between many organs, hormones, immune, cells, and long term biological responses that are hard to recreate in a lab. These technologies can also be expensive and technically challenging to use. Because of that, they are not likely to replace every form of animal testing immediately. However, they are clearly becoming stronger tools that can reduce the need for animals and improve how researchers study human biology.

Overall, 3D organoids and microfluidic organs-on-chips are helping move science in a better direction. By using human derived iPSCs, they create more realistic models for studying drug safety and toxicity than many animal models can provide. While they still have limitations, they represent a major improvement in how scientists can test drugs and understand disease. As these technologies continue to develop, they will likely play an even bigger role in making research more accurate, more ethical, and more human focused.