

Biotech and Medical AI: First Day's Assignment (Jan. 19, 2021)

READING. Before class, read any four of the following short articles and come to class prepared to discuss them:

1. **AI software could displace 47% of workers:** Pham et al, “The Impact of Robotics and Automation on Working Conditions and Employment,” IEEE Robotics and Automation Magazine (June 2018) *See reading Intro1 on Course Web Page*
2. **Lawyers and other skilled workers are not safe from AI-related job loss:** Kevin Finneran, “Overdetermined,” Issues in Science & Technology (Vol. xxv, Fall 2018), at <https://issues.org/overdetermined/>
3. **Non-transparency of AI Software:** Cliff Kuang, Can AI be Taught to Explain Itself? New York Times (Nov. 21, 2017) *available at:* <https://www.nytimes.com/2017/11/21/magazine/can-ai-be-taught-to-explain-itself.html>
4. **Is anybody regulating this stuff? Gene-edited and synthesized food falls into regulatory gaps:** Dan Charles, “Will Gene-Edited Food be Government Regulated?” NPR (May 10, 2019), at <https://www.npr.org/sections/thesalt/2019/05/10/717273970/will-gene-edited-food-be-government-regulated>
5. **Gene editing offers medical miracles for patients who can pay millions of dollars:** Carolyn Y. Johnson & Brady Dennis, “Gene Therapies offer dramatic promise but shocking costs,” The Washington Post (Nov. 14/15, 2015), *See reading Intro 5 on Course Web page* or see https://www.washingtonpost.com/business/economy/gene-therapies-offer-dramatic-promise-but-shocking-costs/2015/11/11/01f11cf0-824b-11e5-9afb-0c971f713d0c_story.html
6. **Gene editing has unresolved safety risks:** Sharon Begley, “Potential DNA damage from CRISPR has been seriously underestimated, study finds,” StatNews (July 6, 2018), at <https://www.statnews.com/2018/07/16/crispr-potential-dna-damage-underestimated/>
7. **Human rights impacts of AI and big data:** Molly Galvin, “Human Rights in the Age of Social Media, Big Data, and AI,” National Academies of Science, Engineering, and Medicine News (Sept. 23, 2019), at <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=9302019>
8. **Ultrapersonalized medicine:** Gina Kolata, “Scientists Designed a Drug for Just One Patient. Her name is Mila,” New York Times (Oct. 9, 2019), at <https://www.nytimes.com/2019/10/09/health/mila-makovec-drug.html?action=click&module=Editors%20Picks&pgtype=Homepage>

SLIDES Intro to FDA-Part I. I also will use some slides to introduce basic concepts about the Food and Drug Administration. An electronic copy is provided on Canvas. Download or print a copy if you like to have them handy during class.

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/325770874>

The Impact of Robotics and Automation on Working Conditions and Employment [Ethical, Legal, and Societal Issues]

Article in IEEE Robotics & Automation Magazine · June 2018

DOI: 10.1109/MRA.2018.2822058

CITATIONS

6

READS

2,426

5 authors, including:



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Some of the authors of this publication are also working on these related projects:



Spirulina biomass production, Phycocyanin Extraction, Algal culture collection [View project](#)



Large Scale Selective Laser Melting [View project](#)

The Impact of Robotics and Automation on Working Conditions and Employment

By Q.-C. Pham, R. Madhavan, L. Righetti, W. Smart, and R. Chatila

As roboticists, we like to think that the fruits of our research—robots that are faster, more efficient, more agile, and more intelligent—can only benefit humanity. While this is certainly true for exploratory or disaster intervention robots, the case is more controversial for other types of robots such as those used for military purposes, as discussed in the previous article in the series [7]. In this article, we provide a quick overview of the concerns raised by the accelerated introduction of robotics and artificial intelligence (AI) technologies in all economic sectors and, in particular, its effects on working conditions and employment.

Robotics and Automation in the Workplace

Robots, like any machines introduced into the production process, have contrasting effects on workers. On the one hand, they can eliminate some harsh, unhealthy, or dangerous tasks. Consider for instance, the welding process in car manufacturing. Welding is certainly a hazardous activity for workers to perform, with deleterious short- and long-term effects ranging from irritations of the eyes, nose, ears, throat, and chest to pulmonary infections, heart diseases, and lung and throat cancers. The robot-based automation of welding in modern car manufacturing lines has significantly reduced health problems caused by welding. On the other hand, precisely

The IEEE Robotics and Automation Research and Practice Ethics Committee (RARPEC) is intended as a platform to exchange ideas and discuss the impacts and practice of robotics and automation (R&A) technologies in research, development, and deployment that appear to pose ethical questions for humanity. With increased awareness and controversies surrounding R&A, RARPEC is publishing a series of opinion pieces that will focus on separating hype from reality by providing an objective and balanced treatment of technological, ethical, legal, and societal perspectives. Second in the series, this piece focuses on topics related to robots, jobs, and workforce development. Please send your feedback and suggestions to the chair of the committee, Raj Madhavan, at raj.madhavan@ieee.org. We look forward to your comments!

because robots can automatically perform some tasks, they render the workers who previously performed those tasks “redundant” for production processes. This has multiple adverse effects for workers.

For example, workers rendered redundant by robots face the risk of being laid off. Since the first machines were introduced on a large scale at the beginning of the 19th century (the First Industrial Revolution), the layoff of redundant workers has been a common practice. An early and particularly tragic episode was the introduction of power looms in the United Kingdom during the first few decades of the 19th century. Skilled weavers were suddenly put in competition with machines that could weave better and faster. Facing wage reduction or replacement by machines operated by cheaper, unskilled workers, desperate weavers (later known as *Luddites*) waged a campaign of destruction targeted at the newly introduced machines. The response by the owner class was harsh: seventeen Luddites were hanged, many others were imprisoned, and the movement was quickly dispelled.

These days, even though strict labor regulations and strong workers’ organizations in most developed countries may offer some protection against or procure compensation in the event of layoffs, such technological layoffs and their adverse effects on the lives of the concerned workers seem inevitable. Indeed, when the management of a company considers introducing robots, its chief concern is not whether the robots are based on a fancy new technology or whether they will improve workers’ welfare; it is profitability. In this view, keeping redundant workers simply does not make economic sense.

Additionally, workers who retain their jobs alongside robots might not always see their working conditions improve. Consider, for instance, the Amazon warehouses into which robots have been introduced on a massive scale over the past few years; because the robots are so fast and so consistent, their pace can be set arbitrarily and is, in fact, imposed on the workers. A journalist working undercover in an Amazon warehouse testifies:

Alone in a locked metal cage, ten feet from my nearest colleague,

a robot approaches from the shadows and thrusts a tower of shelves toward me. I have nine seconds to grab and process an item to be sent for packing, a target of 300 items an hour, for hour after relentless hour. As I bend to the floor then reach high above my head to fulfill a never-ending stream of orders, my body screams at me [8].

Far from the image of robots serving humans, the reality is, in fact, the other way round: "... (human) staff are just cattle, there to serve robots" [8].

But would the increased work intensity be compensated for by higher salaries or shorter working hours? In fact, a detailed study of the effects of robot densification in 14 industries across 17 developed countries during the period of 1993–2007 shows that low- and middle-skilled workers actually suffered salary reduction with the introduction of robots, as illustrated in Table 7 in [5]. The same study shows that there was no significant reduction in the number of working hours.

Global Effects of Robotics and Automation: Toward a Jobless Society?

As discussed in the "Robotics and Automation in the Workplace" section, the impact of robotics and automation on the welfare of individual workers is far from entirely positive, but what are its long-term effects on all of society, particularly with regard to employment?

Interestingly, only a few decades after the Luddite revolt, the perspective of entirely automatic production, without any human intervention, started to be formulated. Andrew Ure, an early business theorist, thus contemplated "the most perfect manufacture [...] which dispenses entirely with manual labor" [9]. That perspective has not, however, materialized. As more tasks became automated, an even larger number of new tasks, made necessary by new products or entirely new economic sectors, was created that required human labor.

Yet, due to the rapid progress of robotics and AI technologies in the past few years, the perspective of a jobless

society, in which all work is performed by robots and no jobs are left for humans, has begun to capture considerable attention from the general public. Alarmist articles about a jobless future abound in the mainstream media, based significantly on scholarly literature. For instance, a widely cited report by Oxford economists predicts that up to 47% of total U.S. employment is at risk of being taken away by automation [4]. In a recent and well-documented book, technologist Martin Ford argues that, contrary to the development of automation up until now, automation today, because of its cognitive capability, carries an actual threat of massive job destruction over the coming decades [3]. However, there are also studies that make much less dramatic predictions. In fact, as highlighted in a recent *MIT Technology Review* survey, there is no consensus among economists and technologists about the degree and timeline of job eliminations resulting from automation [10]. Furthermore, the effects of robotics and AI on the norms of work and employment, and the associated concerns in developing economies (the so-called global south), are even less well understood because their societal acceptance and assimilation differ significantly between developed and developing economies. In labor-intensive economies (for example, the BRICS countries, i.e., Brazil, Russia, India, China, and South Africa), the effects of automation would be felt much more steeply in the coming decade. While labor may still be cheap in developing economies, automation in developed countries will offset this advantage, thereby possibly resulting in significant adverse effects on workforces in developing countries.

The number of robots in factories has been rising quickly, and robotics technologies have been introduced into many sectors beyond manufacturing, e.g., surgical or rehabilitation robots in hospitals, service robots, self-driving cars, and so on. However, from a robotists' perspective, there is still a very long way to go before robots can totally replace humans. For example, outside of the structured environments of factory assembly lines, robot locomotion and

manipulation capabilities are still very limited. During the 2015 Defense Advanced Research Projects Agency Robotics Challenge, robots (teleoperated by humans and so not even autonomous!) from the best research labs around the world had trouble performing tasks that most humans would find trivial. Even the simple task of grasping and manipulating a previously unknown object in-hand is still the subject of intense academic research. Moreover, the robots already deployed in factories still require an enormous amount of reprogramming when facing a slightly different task. They are far from being able to automatically learn to perform new tasks by themselves or from human demonstration.

Finally, the discussion of automation and employment should not be centered only on the number of jobs lost; it should also deal with the changing nature of work because of the automatability and functional description of tasks. In the Fourth Industrial Revolution, the emphasis is on how machines and humans can work together so that repetitive and dangerous tasks can be relegated to machines and automated systems. This augmented collaborative workforce is the wave of the future and has enormous implications for employment in the automation age. It will redefine the relations between workers, their crafts, and their working environments. On the one hand, workers can focus on aspects that require creativity, social skills, and emotional intelligence; on the other, this could also have a dehumanizing effect if workers' activities are subjugated to robots' behaviors.

Proposed Solutions to Address Unemployment Caused by Automation

Although the degree and timeline of job eliminations caused by automation are still debated, there is a consensus that, in the present global context of stagnant and interdependent economies, automation will inevitably take away a significant number of jobs. This means that, in the next few years and decades, many workers will lose their jobs to robots, while those keeping their jobs will experience

increased physical and psychological pressure and still more will face unemployment due to the lack of jobs. A number of solutions have been proposed to address these problems.

An important consideration is to raise the level of workers' education (both initially and continuing) so that they can undertake the higher-level jobs required by automation. Training programs to develop new, requisite skill sets available across the spectrum of the workforce, and not just for low-skilled workers, could be mandated. Such programs could be funded by public-private partnerships and made available for workers who are still employed and those who are in between jobs.

Universal basic income (UBI) is another concept proposed to address technological unemployment, with all of a country's citizens or residents unconditionally receiving sufficient regular amounts of money that will enable them to live. Additionally, there would be no requirement for people to work or look for work. There are many versions of UBI, differing widely in terms of the proposed income amount and the funding source. In any case, for such a system to provide decent living conditions for everyone in a country (and, beyond, in every country), the amount of funding required is likely to be very significant. As a result, there is a significant and complex debate about how UBI could be funded, whether such a system could be sustainable at all, and the effects it would have on the economy.

The notion of robot taxes has been proposed as another alternative to deal with the potential unemployment created by automation. The basic idea, as suggested by Bill Gates [1], is to tax corporations and entities deploying robots that cause job losses. The tax income could then be used to offset the economic hardships experienced by laid-off workers or retrain them so that they can be reassimilated into the workforce. In that vein, a motion (eventually rejected) in the European Union Parliament in 2017 proposed "levying tax on the work performed by a robot or a fee for using and maintaining a robot should be

examined in the context of funding the support and retraining of unemployed workers whose jobs have been reduced or eliminated" [2]. Robot taxes have certainly met criticisms from a number of economists. For instance, Larry Summers [6] argued that there are no fundamental differences between robots and any technologies that may cause job losses (including Bill Gates's software); yet there are no specific taxes on such technologies. Thus, taxing robots would amount to another tax on capital, which most capitalists would oppose.

More generally, socioeconomic, political, and resource constraints should be carefully considered when emerging technologies are deployed because there is a potential for unintended consequences such as tilting economic and power structures to unduly benefit certain segments of society, resulting in new gaps and/or exacerbating existing inequities. There are time-sensitive challenges regarding how developing nations, with their potentially low-technology classroom-centric curricula, can be provided with the technical expertise that would allow for the introduction and absorption of these cutting-edge technologies.

Robotics and automation carries the wonderful promise of liberating humanity from toil. In an ideal society, most of the repetitive, unhealthy, and uninteresting work would be fulfilled by robots, while humans would spend a limited amount of time every day on work (including deciding what the robots should do) and the rest of the time on creative activities. From a technical viewpoint, this future is certainly possible, yet both the current situation and the outlook pictured by many reports are gloomy. Robots now tend to be perceived by a portion of the general public as a threat, instead of as a fantastic liberation tool. Why is this so?

In the current economic system where robots are owned by a minority, the gains in productivity they permit (e.g., higher wages and fewer working hours) are not likely to be shared by the working majority; rather, robots would be seen as the reason for humans' job losses. Therefore, to reach the ideal

society that most robotics researchers have in mind, the notion of who owns the robots, the working majority or a minority of capitalists, might just be the decisive question.

References

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Gene therapies offer dramatic promise but shocking costs

By [Carolyn Y. Johnson](#) and
[Brady Dennis](#)

November 11, 2015

For most of her life, Allison Corona lived in a world dimmed by bad genetic luck. A disease called Leber's congenital amaurosis left her legally blind at age 4. She could not navigate the short distance from her driveway to her front door after dusk.

Three years ago, Corona, now 23, received an experimental medical treatment aimed at fixing the faulty genes in her eyes. Researchers at the Children's Hospital of Philadelphia injected viruses carrying a good copy of her errant gene into her right eye and, nine days later, her left eye.

The world around her, once dark and austere, soon grew brighter. Her vision is still far from perfect, but for the first time, she sees that paper towels have texture. She marvels at the velvet floral wallpaper that covers her bedroom wall. She takes a college class that gets out at 10:30 p.m. and no longer fears getting stranded in the night.

"Things became much more beautiful for me," Corona said.

First tested in patients [a quarter-century ago](#), gene therapy — a risky approach aimed at fixing the malfunctioning genes at the root of some diseases — is finally emerging from its own darkness after weathering high-profile tragedies, including the [death of a teenage patient](#).

As it evolves from experimental to applied medicine, gene therapy might soon find itself steeped in a new controversy: soaring drug prices. No therapy is approved yet in the United States, so discussions about price — as well as crucial questions about how much patients will pay directly — are hypothetical. But industry leaders are already talking about ways to get ahead of potentially massive one-time price tags that could make insurers and patients balk.

A gene therapy approved in Europe in 2012 costs close to \$1 million, and prices are expected to follow suit in the United States. The therapies in the pipeline are mostly for rare genetic diseases: sickle cell, hemophilia or immune deficiency. Their likely high prices stem from the expected value; unlike drugs that a person takes regularly, gene therapies are designed to be given once and have lasting effects.

But everyone involved anticipates the potential backlash against a seven-figure price tag, which is leading to radical proposals. Instead of paying for a treatment all at once, insurers and patients could make installment payments as long as the therapy works, similar to a mortgage on a house. Some researchers are adding up the cost of the traditional treatments that a patient will be able to avoid each year to determine a price that, although high, could lead to savings for the health-care system.

To Corona, the gift of vision is something approaching a miracle. But how much is that miracle worth in dollars?

In the 1980s, a daring idea seized the imagination of scientists and physicians. What if they could design a drug that wouldn't just treat the symptoms of a disease caused by a mutant gene, but could instead replace the gene with one that worked normally?

Gene therapy was technically difficult but conceptually simple. Scientists would modify a virus so that when it infected a cell, it would ferry in the correct version of a broken gene.

If the process worked, doctors would have a powerful weapon against rare but devastating maladies such as cystic fibrosis and "bubble boy" disease, which leaves children without immune defenses.

As basic research moved forward, excitement about gene therapy soared. But, as with many new biomedical technologies, that initial exuberance would die down as the powerful idea of replacing broken genes collided with the inherent complexity of human biology. For gene therapy, the blip wouldn't be just a scientific setback fought out on the pages of scientific and medical journals, but an international scandal in which patients were harmed and public faith was shaken.

In 1999, an Arizona teenager named Jesse Gelsinger died after he experienced an unexpected, severe immune reaction while participating in a clinical trial of gene therapy led by researcher James M. Wilson at the University of Pennsylvania.

“Everybody sort of stepped back and said, ‘Okay, we really have to consider, now that gene therapy has lost its innocence, what are we doing here? And what are the ways in which, if we’re going to do additional experiments, we don’t let this happen again?’” Francis Collins, director of the National Institutes of Health, said recently. “It was big; it was very big. I would not be surprised if some young scientists who were thinking of going down this path decided to do something else.”

Wilson became the subject of legal action and scathing media coverage. The government restricted his work on human subjects. Lawmakers on Capitol Hill held hearings to probe the lack of oversight and the ethical lapses that had marked some gene-therapy trials. Gelsinger’s father, Paul, told one Senate panel in 2000, “The concern should not be on getting to the finish line first but on making sure no unnecessary risks are taken, no lives filled with potential and promise are lost forever, no more fathers lose their sons.”

Also in the early 2000s, a few patients in a French gene-therapy trial developed leukemia. Along with the Gelsinger case, it proved a tipping point. Private investment in the field rapidly dried up, and it entered what Cowen & Co. Managing Director Phil Nadeau calls a “nuclear

winter.” Regulators halted dozens of trials. To many, gene therapy seemed close to dead; a field of science that had been on a fast track appeared to have been relegated to little more than an interesting academic pursuit for a small cadre of researchers.

With less money, less hype, and much more humility and caution, Wilson and other researchers searched for ways to improve the safety of the viruses used to insert genes.

“It was a realization that the technology we had, which was on the shelf when we began the field, was inadequate for this field to move forward in any substantive way,” Wilson recalled. “It was really to go back to the drawing board, for me. That was a complete reorganization of what I was doing, how I was doing it, the kind of people who worked for me. It was a complete reboot.”

Gene therapy’s comeback started with a trickle. In 2008, researchers reported that a small number of patients with an inherited form of blindness gained modest improvements in vision with gene therapy. Not long after, gene therapy restored immune function in eight of 10 children with typically lethal “bubble boy” disease.

Katherine High, a researcher at the Children’s Hospital of Philadelphia who worked on one of the early blindness trials, started getting cold calls from investors and from pharmaceutical companies, asking if they could partner with her. Then the team of experts she had assembled in Philadelphia began to get job offers.

“I remember very clearly, around 2011, I began to think to myself, ‘If we don’t form a company so we can all stay together, I’m going to lose these people,’ ” High said. She co-founded Spark Therapeutics, which went public this year and is sponsoring the trial in which Corona

participated. The company is expected to put its blindness therapy before U.S. regulators, likely next year.

It's one of many companies with treatments in the pipeline. UniQure's drug, Glybera, in 2012 became the first gene therapy approved in Europe, for a rare metabolic disease. Bluebird Bio, a biotechnology company that went public in 2013, is developing a variety of gene therapies, including a treatment for a genetic blood disease. Regeneron, where Wilson serves as chief scientific adviser, went public in September.

"This is only the beginning of what's going to be a remarkable era in medicine," Wilson said. "But if it's the beginning, that suggests there's significant room for improvement. That means there will be failures and there will be successes."

On the precipice of having a treatment finally make it onto the market, gene therapy faces yet another controversy: price.

Although much of the current outrage has been spurred by companies that take old drugs and jack up their prices, the potential sticker shock from a million-dollar drug — even if it's for a previously incurable disease — is sure to raise some of the same questions from politicians and the public.

Nadeau, of Cowen & Co., said his firm has estimated that Spark Therapeutics' gene therapy will cost \$500,000 per eye. A study published last year in the journal [Nature Biotechnology](#) examined current health-care spending on hemophilia B and found that a gene therapy could conceivably be priced as a one-time payment of \$4 million to \$6 million. The authors argued that paying \$150,000 a year as long as the drug works could potentially save the health-care system money.

Spark Therapeutics chief executive Jeffrey Marrazzo is reluctant to talk about a dollar figure, but he does think it's time to consider changes in the way the health-care system pays for treatments.

The options being discussed include a down-payment model, with annual payments. University of Washington economist Anirban Basu has proposed an alternate health currency, [HealthCoin](#), that insurers pay for when buying a cure and then sell to another insurance plan at a depreciated price if a patient switches insurers or becomes eligible for Medicare.

The feasibility of these plans remains uncertain. But gene-therapy executives are arguing that, even at unprecedented prices, their drugs will save the health-care system money — and carry other benefits.

“How do we recognize that there's truly something that's important and valuable to people, not only to have certain aspects of their vision restored, but . . . to have it done once and then have the ability to go on with their lives?” Marrazzo said.

Corona, who excitedly woke up her family in the middle of the night when she read about the possibility of gene therapy years ago, didn't have to pay for her treatment, because she was part of a clinical trial.


But she said her family would have found a way to get her the therapy if it had already been on the market, even if it meant battling an insurance company or taking out a loan. After all, she

said, it's not only about seeing better. She now feels like a happier, more confident person. That part feels priceless.




105 Comments

Carolyn Y. Johnson

Carolyn Johnson is a science reporter. She previously covered the business of health and the affordability of health care to consumers. [Follow](#) 

Brady Dennis

Brady Dennis is a national reporter for The Washington Post, focusing on the environment and public health issues. He previously spent years covering the nation's economy. Dennis was a finalist for the 2009 Pulitzer Prize for a series of explanatory stories about the global financial crisis. [Follow](#) 

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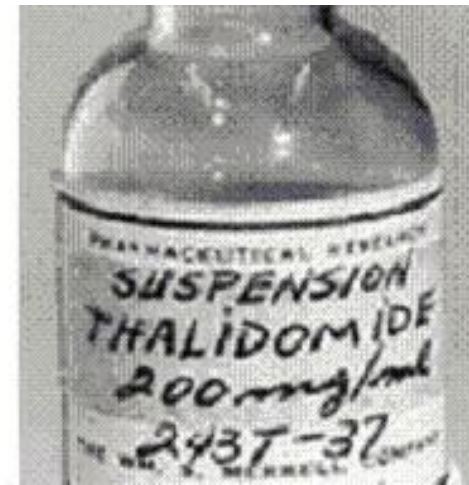
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FDA Basic Concepts

Part 1



Topics

- What is Food & Drug Law?
- Why is it important?
- Where does FDA get its power and how does FDA exercise that power?
- What does the FDA do?

What Does FDA Regulate?



Food



Drugs



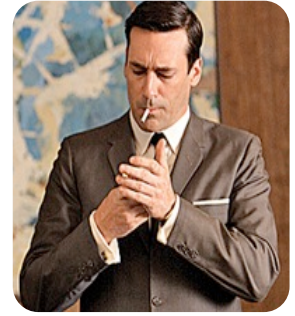
Cosmetics



Devices



Biologics



Tobacco

Where does FDA fit in the federal government?



Where does FDA fit in the federal government?



Why is the FDA important?

- Regulates quarter of our retail economy
- FDA is a consumer safety regulator, not an economic regulator
- Aims to ensure products are safe, effective
- Evaluates new technologies, monitors old ones
- Handles emerging public health issues
- Sets standards having global influence

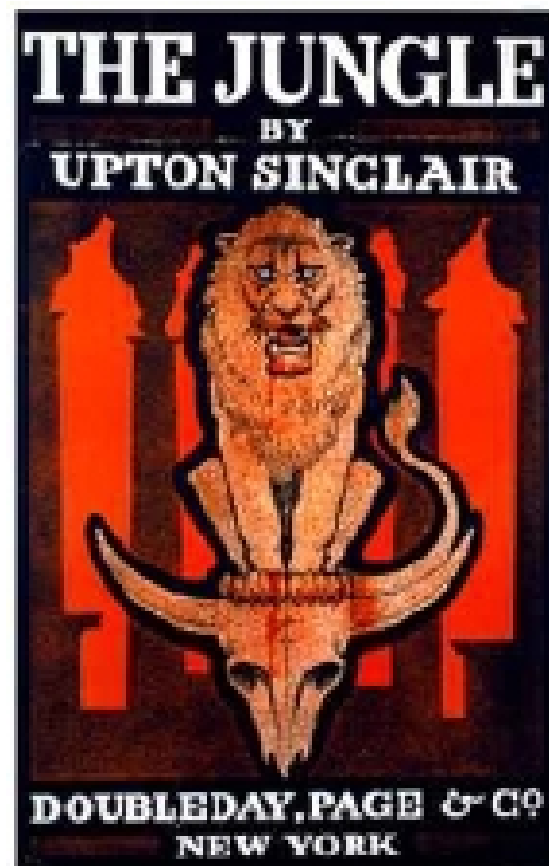
How did the FDA evolve?

- 1848 U.S. Patent Office
- 1862 U.S. Department of Agriculture (USDA)
- 1890 USDA Division of Chemistry
- 1901 USDA Bureau of Chemistry
- 1927 Food, Drug, and Insecticide Admin.
- 1930 Food and Drug Administration (FDA)



Where does FDA get its power?

| | |
|---------|---|
| 1902 | Biologics Control Act |
| 1906 | Pure Food and Drug Act |
| 1938 | Food, Drug, and Cosmetic Act (FDCA) |
| 1962 | Drug Amendments (Kefauver-Harris) |
| 1976 | Medical Device Amendments |
| 1984 | Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman) |
| 90s-00s | FDAMA, PDUFA, MDUFMA, FDAAA, FDASIA |



What does the FDA do?

| General authority | Enforcement authority |
|------------------------------------|------------------------------------|
| Promulgates regulations | Inspects facilities, takes samples |
| Reviews marketing applications | Seizes products |
| Inspects facilities | Seeks injunctions |
| Monitors imports | Recalls products |
| Monitors advertising, labeling | Initiates criminal prosecutions |
| Issues reports | Seeks civil penalties |
| Issues guidances | Seeks debarment |
| Interacts with industry, consumers | Issues “Warning Letters” |
| Cooperates with other agencies | Issues negative publicity |

FDA has separate Centers that implement different statutes



CDER Human Drugs



C | B
E | R



+ more centers

Recurring themes

- Science vs. politics?
- Checks and balances on FDA
- Risk regulation & handling uncertainty
- Inter-agency cooperation

Skills you will cultivate

- How to interpret statutes, regs
- How to handle regulatory matters for clients or for yourself
- How to research regulatory matters

What FDA Regulates

Defined categories

- Food/Food Additives/
Dietary Supplements
- Drugs
- Biologics (not just old-fashioned biologic drugs like penicillin, but many of the coolest emerging technologies)
- Devices (including diagnostics and software)

FDA's jurisdiction

Definitions matter

- FDA regulates product categories
- Categories determine the regulatory requirements a product developer or manufacturer must comply with

Definitions are flexible, giving FDA discretion

- *United States v. Bacto-Unidisk* (U.S. 1969)

What is a “food”?

- (1) articles used for food and drink for man or other animals;
- (2) chewing gum; and
- (3) articles used for components of any such article.

FDCA § 201(f)

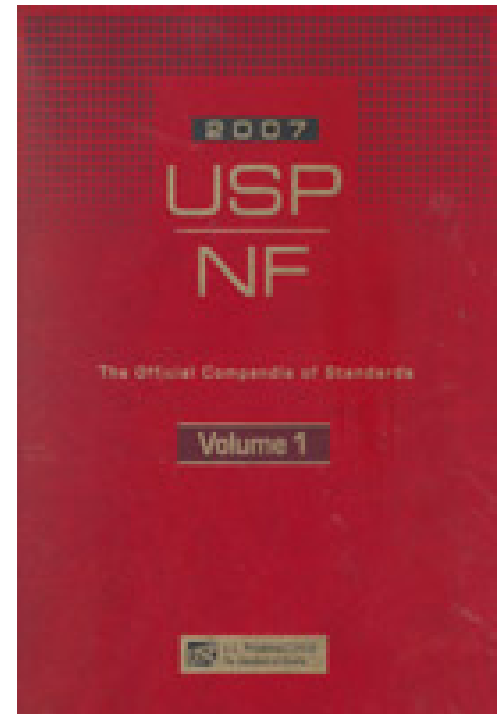
What is a “drug”?

The term ‘drug’ means:

- (A) articles recognized by an official medical compendium;
- (B) articles intended to diagnose, cure, mitigate, treat, or prevent disease;
- (C) articles (other than food) intended to affect the structure or function of the body;
- (D) articles intended to be used as components of (A), (B), or (C).

Inclusion in official medical compendia

- Recognized compendia:
 - U.S. Pharmacopoeia (USP)
 - National Formulary (NF)
 - Homeopathic Pharmacopoeia of the U.S. (HPUS)
- Inclusion is not dispositive
 - *U.S. v. Ova II* (D.N.J. 1975)



What is a “drug”?

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Intended use

- “The objective intent of the persons legally responsible for the labeling of drugs”
- “Determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article”
 - Labeling claims
 - Advertising matter
 - Oral or written statements

21 C.F.R. § § 201.128 (drugs), 801.4 (devices)

Defining “device”

“Device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

- (1) recognized in an official medical compendium;
- (2) intended to diagnose diseases or other conditions or to cure, mitigate, treat, or prevent diseases, etc; or
- (3) intended to affect the structure or any function of the body

and which does not achieve its primary intended purposes through chemical action within or on the body ... and which does not depend upon being metabolized....

Biologics

Public Health Service Act (PHSA) § 262(i):

- a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound)
- applicable to the prevention, treatment, or cure of a disease or condition of human beings
- See updated definition in class handout

Where does FDA law come from?

- Statutes enacted by Congress (21 USC)
- FDA rulemaking – regulations (21 CFR)
- FDA guidance
- Judicial review of FDA decisions
- Agency practice
- Constitutional constraints

The rulemaking process

Agency proposes regulation

OMB reviews under E.O. 12866

Proposed rule published in Fed.
Reg.

Public comment period

OMB re-reviews

The rulemaking process

Final regulation published in Fed. Reg.



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graph TD; A[Final regulation published in Fed. Reg.] --> B[Final regulation responds to public comments (preamble), sets effective date]; B --> C[Agency submits to Congress and GAO per Congressional Review Act]; C --> D[New regulation placed in updated CFR];
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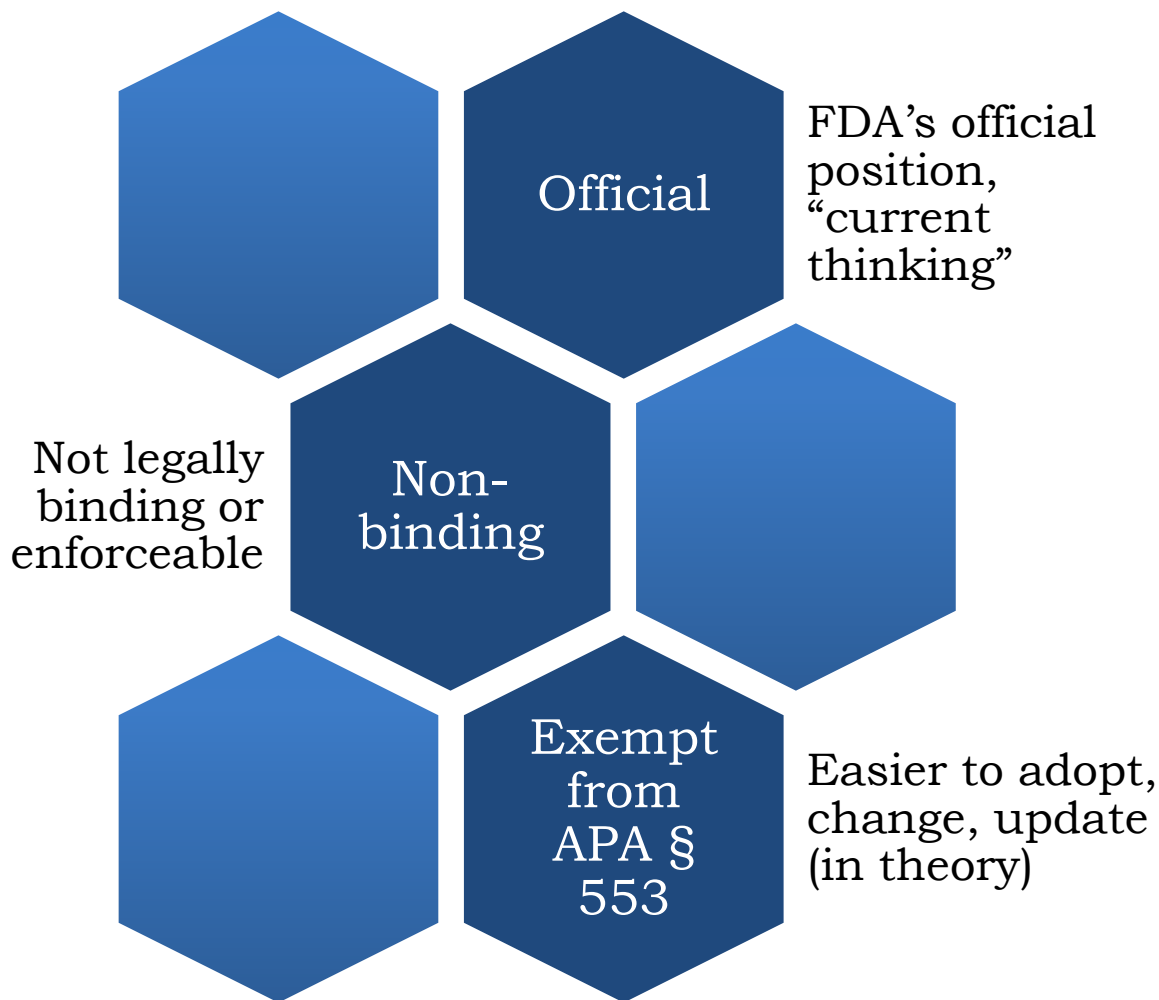
The diagram illustrates the rulemaking process as a four-step flowchart. Each step is contained within a colored rectangular box, and the steps are connected by downward-pointing arrows. The boxes are arranged in a descending staircase pattern from top-left to bottom-right. The colors of the boxes are dark blue, purple, magenta, and red, respectively.

Final regulation responds to public comments (preamble), sets effective date

Agency submits to Congress and GAO per Congressional Review Act

New regulation placed in updated CFR

2. The rise of guidance



2. The rise of guidance

Food and Drug Administration, HHS

§ 10.115 Good guidance practices.

(a) *What are good guidance practices?* Good guidance practices (GGP's) are FDA's policies and procedures for developing, issuing, and using guidance documents.

(b) *What is a guidance document?* (1) Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

(2) Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.

21 C.F.R. § 10.115

TITLE 21—FOOD AND DRUGS

(h) Guidance documents

(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

21 U.S.C. § 371(h); FDCA § 701(h)

3. Judicial review of FDA actions

TITLE 5—GOVERNMENT ORGANIZATION AND EMPLOYEES

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

3. Judicial review of FDA actions

Chevron

Courts should defer to reasonable agency interpretations of statutes they are charged with administering. *Chevron* two-step:

1. Is the statute ambiguous?
2. If so, is agency interpretation reasonable?

Skidmore

Defer to agency decision in proportion to its “power to persuade”

Mead

Chevron step zero. Does this agency decision warrant *Chevron* or *Skidmore* deference?

Auer

Defer to agency interpretation of its own regulations, unless “plainly erroneous”