
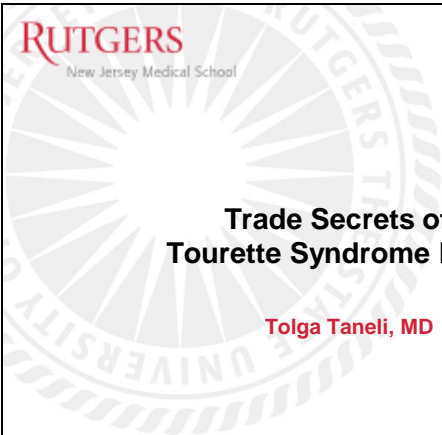


Slide  
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## Trade Secrets of a Tourette Syndrome Doctor

**Tolga Taneli, MD**

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2

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## Objectives

- How are drugs approved by the FDA?
- How do we pick medicines?
- How should my providers collaborate?
  - What are implications of the HIPAA Law?

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4



“Taking care of patients  
is different from  
taking care of disease.”

Eugene A. Stead, Jr.

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5



### Drug Discovery & Approval

Federal laws require that pharmaceutical manufacturers show their products are **safe** and **effective** in order to market these drugs in the USA. This is enforced by the Food and Drug Administration (FDA.)

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6



### Drug Discovery & Approval

The FDA approval process grants **marketing exclusivity**, permitting manufacturers to profit substantially, but also to give impetus for further drug discovery.

After the marketing exclusivity for the **“brand name”** drug expires, the drug may be manufactured as a **generic** product.

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Slide  
7



## Drug Discovery & Approval

While some extensions may apply, patent protection is generally enjoyed for 20 years from the date of filing.

- Hatch-Waxman Act: Up to five years for time lost in the FDA approval process, three years for a new claim for existing pharmaceutical
- The Orphan Drug Act: drugs for disorders affecting fewer than 2,000 people annually may receive sole market rights for 7 years from the date of product approval
- The Best Pharmaceuticals for Children Act: Six months "**pediatric exclusivity**" for demonstrating efficacy in children

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Slide  
8



## Drug Discovery & Approval

- Why is marketing exclusivity important?
  - A "**blockbuster drug**" will have annual revenue of several billion dollars.
  - Annual sales of the most profitable drug, Abilify (aripiprazole) reached **\$6.9 billion** this year.
  - Pfizer, the most profitable pharmaceutical company made **\$22 billion in profits** from \$57 billion in sales this year. That is a 42% profit margin. The top 10 pharmaceutical companies average 19% profit margins.

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9



## Drug Discovery & Approval

The "Best Pharmaceuticals for Children Act" grants manufacturers six months of "**pediatric exclusivity**" if the demonstrate that the medicine is safe and effective in children.

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Slide  
10



## Drug Discovery & Approval

- For every drug that reaches the market, a pharmaceutical company will have identified **5,000 to 10,000** compounds in **drug discovery**, of which only **250** will make it to **preclinical trials**. The process will have taken up to six years, leading to about **five** compounds identified for **clinical trials**.
- An "**Investigational New Drug**" (IND) application is then filed with the FDA for each compound to enter **clinical trials**.

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Slide  
11



## Drug Discovery & Approval

- For every drug that reaches the market, a pharmaceutical company will have identified **5,000 to 10,000** compounds in **drug discovery**...
- of which only **250** will make it to **preclinical trials**...
- leading to about **five** compounds identified for **clinical trials**.

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12



## Drug Discovery & Approval

- Clinical trials will last 6-9 years and include:
  - Phase 1: Safety studies in (20-100) healthy volunteers
  - Phase 2: Initial efficacy studies in (100-500) patients
  - Phase 3: Broader efficacy assessment in (1,000-5,000) patients
- A "**New Drug Application**" (NDA) is filed with the FDA when the sponsor believes that enough evidence on safety and efficacy has been obtained for a particular **indication**. If the NDA is approved, the drug may be marketed in the USA. The entire process will have taken several hundred million dollars and 16 years, on average.
- There is mandatory post marketing surveillance, sometimes called "Phase 4."

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13



## Drug Discovery & Approval

- When all is said and done, the pharmaceutical company will have spent several hundred million dollars and 16 years, on average.
- The FDA will then approve this one New Drug for the **indication** for which safety and effectiveness was demonstrated.
- Only one indication need exist. Fiscal forces act on whether new indications will be filed, including the ability to extend exclusivity.

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14



## Drug Discovery & Approval

In brief, the approval process is substantially burdensome to pharmaceutical companies, rigorous, and generally leads to the marketing of effective medicines with predictable side effects.

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Slide  
15



## Best Practices

- The gold standard for the use of a medicine in your child's care is an FDA-approved product used for its FDA-approved "**indication.**"
- The approval process mandates scientific best practices, such as "**double-blind randomized controlled trials.**"

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Slide  
16



## double-blind randomized Controlled trials

- Is the gold standard of study design.
- One group of patients receives the medicine while another receives **placebo** or sham treatment.
- Assignment to each group is **random**.
- The patient and doctor are **blinded** to who receives medicine and who receives placebo.

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Slide  
17



## Prescription Best Practices

- Double-blind Randomized Controlled Trials also give the best evidence for non-FDA-approved medicines
- The data must be interpreted by expert prescribers: for example "**Practice Parameters**" and other analyses.
- The raw data is available to you and your doctor, for example **PubMed**.

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18



## Practice Parameters

- Groups of experts review the evidence available to them.
- A consensus document is created which combines and interprets this data, adding expertise.
- Expert opinion may be swayed by "conflicts of interest."

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Slide  
19



## PubMed

- PubMed ([www.pubmed.gov](http://www.pubmed.gov)) is a resource of the US National Library of Medicine, cataloging millions of citations
- Unlike practice parameters, the data is **new**, but **raw**
- Tutorials are available on the website
- Bring abstracts to your doctor to interpret.
- Doctors with university affiliation will have access to many full articles that may not be available to the general public.

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Slide  
20



## The Time with Your (Child's) Doctor

- Arrive prepared to ask questions
- Bring a notepad and pen
- If you could not follow a recommendation, ask for it in writing
- Ask for explanations:
  - Why did you recommend X?
  - What are possible benefits of X (**target symptoms**)?
  - What side effects are common?
  - Why should we not try Y?
  - May I have a patient hand-out for X?

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Slide  
21



## Past Treatments

- Keep a **journal** of the care of your child
  - Include medicines, preferably bolded or highlighted
  - Include target symptoms, response and side effects
  - Include names and phone numbers of providers
- Obtain full copies of Child Study Team **evaluations**, not just the Individualized Educational Plan (IEP)
- Bring assessment and treatment records to first appointments
- If you used one or few **pharmacies**, ask for print-outs of all medicines dispensed, with as much detail as possible.

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Slide  
22



### Good Providers...

- Don't chase individual symptoms
- Understand comorbidities
- Have a holistic approach to health and happiness
- Collaborate with other providers
- Communicate with schools
- Are responsive to queries about treatment choices
- Are reasonably available
- Make you feel like you are their only patient
  - but should also be forgiven from time to time!

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23



### Good Providers...

- Don't chase individual symptoms
  - Extinguishing all tics is not always the best objective in treatment.
  - Sometimes it is not even the most salient problem.

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Slide  
24



### Good Providers...

- Understand comorbidities
  - Are not blind to where impairment comes from
    - ADHD
      - Executive function deficits
    - ODD
    - Sensory Integration Deficits
    - Mood
    - Anxiety
    - Learning difficulties
    - ...

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Slide  
25



### Good Providers...

- Have a holistic approach to health and happiness
  - Take interest in the child and his/her hobbies and accomplishments
  - Take interest in **siblings**, who are unduly taxed
  - Participate in a strategy to enrich and “realize” the child
  - Are mindful of the needs of the parents
  - Are in it for the long haul!

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Slide  
26



### Good Providers...

- Collaborate with other providers
  - Respect modalities of treatment not in their repertoire
  - Are prepared to review evidence with you for such treatments
- Communicate with schools
  - Will ask to contact teachers
  - Will have recommendations for teachers
  - Will work to reduce stigma at school

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Slide  
27



### A word about teachers

- Teachers work hard during the school year. They have no slack, buffer or fluff; however you wish to word that.
- Their schedules are tight, sometimes more so than doctors.
- Usually extend themselves beyond work hours.
- Nearly every teacher cares to do well by your child.
- They are not healthcare providers, they are educators.
- They are amenable to education!

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28



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REFERRALS AND SERVICES FOR KIDS, FAMILIES AND PROFESSIONALS DEALING WITH TS 908.575.7350

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As many as 1 in 100 kids show signs of Tourette Syndrome - most of them undiagnosed, misdiagnosed and/or misunderstood.

NJCTS provides answers for these kids and their families through referrals to programs and services, education and training so that families, peers and professionals will be better qualified to help those with TS, and support of research programs so that we can find better treatments and a cure.

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Slide  
29

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### Collaboration

- Good TS doctors have friends in other disciplines. When available, work with established colleagues to improve communication (“Who would you recommend?”)
- Offer a list of the names and numbers of all current and past providers to each provider
- Organize “team meetings” in person or by phone
  - Understand billing implications with limits to non-face-to-face encounters
- Fire providers who refuse to collaborate!

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Slide  
30

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### Good Providers...

- Are responsive to queries about treatment choices
  - Do not dismiss your questions
  - At least browse what you bring
  - Apply evidence-based methods to the material
- Are reasonably available
  - Most good doctors ARE busy!
  - If you leave a message, have a clear question
  - Give call back times, including late evening
  - Call back, if you haven't heard

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Slide  
31



## Good Providers...

- Make you feel like you are their only patient... but should also be forgiven from time to time!
  - Accept their sincere apologies (within reason!)
  - Most child psychiatrists have waxing & waning workloads
    - Consider keeping a summer appointment for extra time!
  - Give ample time for prescription refills, but mostly make sure you are good from appointment to appointment.
    - Stimulants cannot be called in, nor dispensed (in New Jersey) for more than three months.

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Slide  
32



## The Big Picture

- Doctor visits are about **illness**.
- Remember to promote **wellness** in your child at home or the doctor's office:
  - Be with them when they are at their best
  - Share achievements with the doctor, so they can praise your child, too!
  - Ask to speak alone for substantial discussions of illness.

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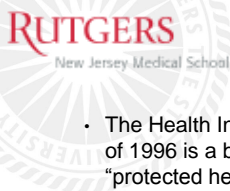
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## HIPAA

- The Health Insurance Portability and Accountability Act of 1996 is a broad law with provisions for the privacy of "protected healthcare information" (PHI.)
  - It has not been kind to care coordination, because the "authorization" requirement is often invoked.
  - Offer to sign authorization forms permitting "coordination of care."
- Family Educational Rights and Privacy Act (FERPA) may apply to health records kept by schools
  - <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf>

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34

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## My Pearl

“If there were no such thing as a side effect,  
there would be no such things as a doctor.”

better said by William Shakespeare:

“...Within the infant rind of this small flower  
Poison hath residence and medicine power...”

Romeo and Juliet, Act 2, Scene 3

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35

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