

Final Year UCSF Health Professional Students’ Knowledge and Perspectives about FDA Regulation: A Survey Study

Kiranjot Kaur¹, Rita F. Redberg, MD, MSc², Aaron S. Kesselheim, MD, JD, MPH³, Steven Woloshin, MD, MS⁴, Sanket S. Dhruva, MD, MHS²
¹School of Medicine, University of California San Francisco, ²Department of Medicine, University of California San Francisco, ³Brigham and Women’s Hospital and Harvard Medical School, ⁴Dartmouth-Hitchcock Medical Center, Dartmouth Institute for Health Policy and Clinical Practice

BACKGROUND

- The FDA regulates drugs and medical devices in the U.S.¹
- Physicians and nurse practitioners have the key responsibility of prescribing medical products and communicating their safety and effectiveness to patients.²
- Pharmacists play a crucial role in advising prescribers and discussing medication safety with patients.³
- Past studies revealed gaps in physicians’ and pharmacists’ knowledge of FDA medical product regulation.^{4,5}
- Although foundational skills about FDA regulation would be learned in health professional education, no prior studies have assessed students’ understanding of medical product regulation or views on curriculum about these topics.

Aim: To assess knowledge regarding drug and device regulation and perspectives about education in curriculum on these topics among final-year students at UCSF Schools of Medicine, Pharmacy, and Nursing (FNP).

METHODS

- Online survey distributed between January 12-April 5, 2024 to 179 medical students, 121 pharmacy students, and 33 FNP students in their final year of training at UCSF.
- A 24-item survey instrument derived from prior surveys and novel questions that was pretested on students at all schools, divided into multiple domains: curriculum, knowledge of FDA approvals, assessment of evidence quality, and demographics.

RESULTS

Exhibit 1: Distribution of survey respondents. Of 333 invited students, 175 (52%) responded.

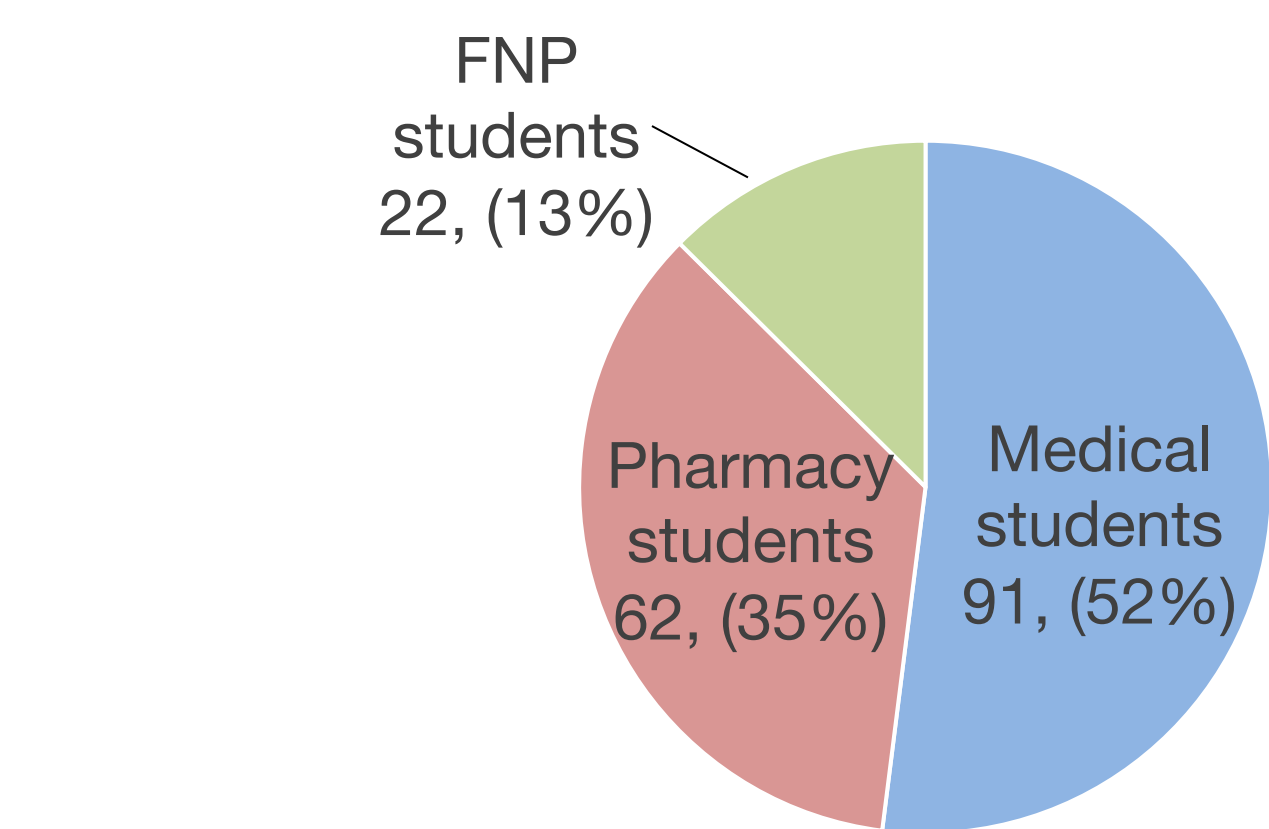


Exhibit 2: (A) Health professional students’ characterization of teaching received on FDA’s drug and medical device approval process and **(B)** views on desired curricular changes.

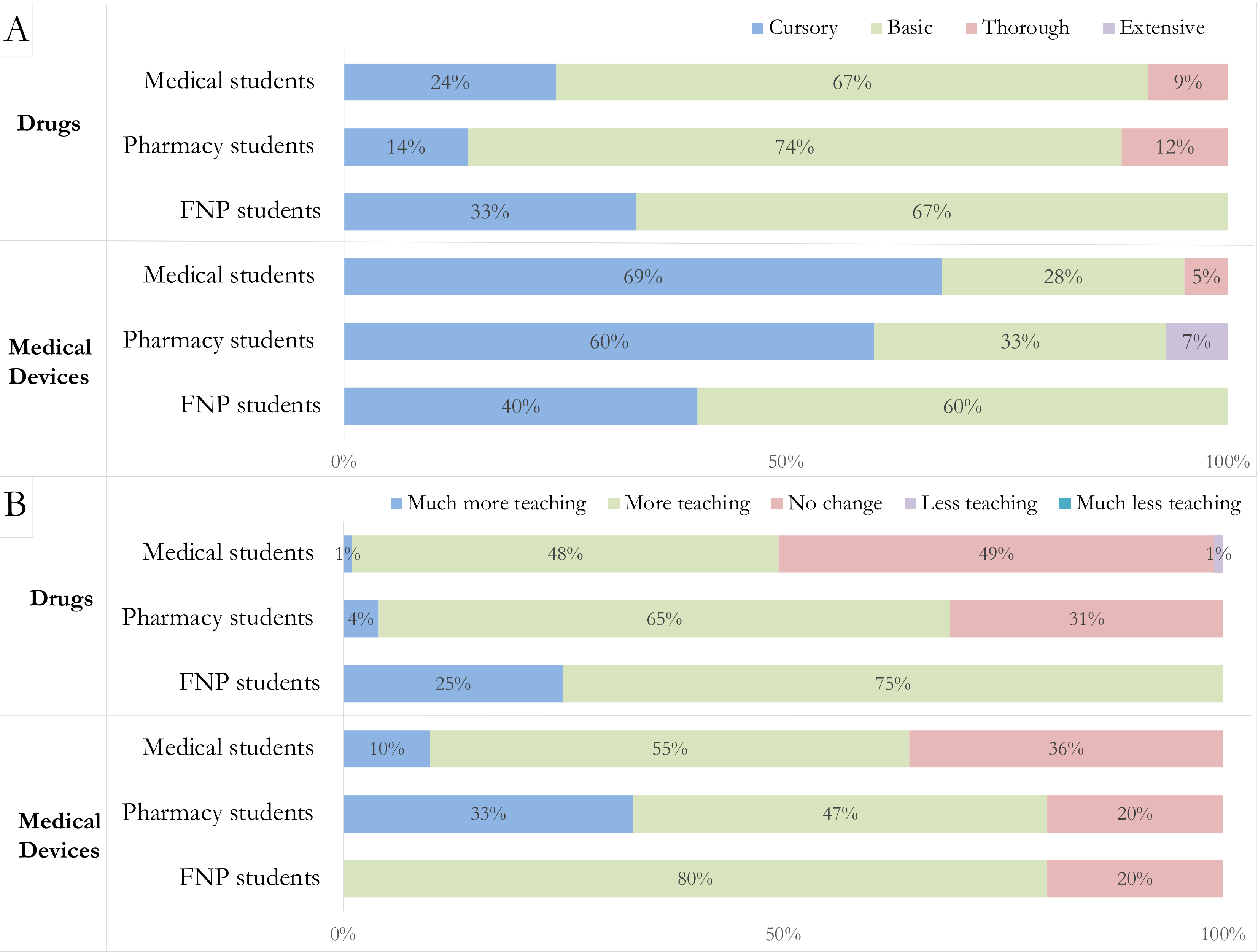


Exhibit 3: Health professional students’ understanding of FDA’s drug and medical device approval process

Understands FDA approval process for...	Drugs (N=164), %	Medical Devices (N=164), %
Extremely well	5 (3%)	2 (1%)
Moderately well	57 (33%)	13 (8%)
Slightly well	74 (43%)	31 (19%)
Not at all well	36 (21%)	118 (72%)

In order to get FDA approval, there must be...	Drugs (N=164), %	Medical Devices (N=164), %
A statistically significant result	12 (7%)	9 (5%)
A clinically important result	23 (14%)	12 (7%)
Both statistically and clinically important results	98 (60%)	57 (35%)
Neither of the results (<i>correct</i>)	5 (3%)	12 (7%)
I’m not sure	26 (16%)	74 (45%)



Exhibit 4: Health professional students’ interpretation of advertisement for a hypothetical drug⁶

The following text appears in a graphic: “Gritagrel—50% reduction in strokes. Gritagrel is a new pill to prevent strokes. People taking Gritagrel had half as many strokes as people taking placebo (i.e. sugar pill). Like any medicine, Gritagrel can have side effects. The most common side effects are headache (5%) and stomach ache (1%).”	
Which would best help you to determine how much a person could benefit from Gritagrel? (N=158),%	
How often people experience side effects	14 (9%)
The chance of stroke for people who do not take Gritagrel ^C	134 (85%)
How many people take Gritagrel	10 (6%)
How recently Gritagrel was developed	0 (0%)
Which would best help you to decide whether your patient will benefit from Gritagrel? (N=158),%	
How many people were in the study	26 (16%)
Age and sex of people in the study ^C	116 (73%)
Whether a doctor confirmed that people had strokes	10 (6%)
Who paid for the study	6 (4%)
Which additional piece of information would be the best evidence that Gritagrel helped people? (N=158), %	
Gritagrel lowered antioxidant levels	4 (3%)
Fewer people died for any reason in the Gritagrel group than in the placebo group ^C	25 (16%)
Many doctors prescribe it	2 (1%)
Fewer people died from strokes in the Gritagrel group than the placebo group	127 (80%)

^C indicates the correct answer
Note: Advertisement and questions from a previously validated questionnaire.⁶

CONCLUSIONS

- Many final-year health professional students have limited understanding of FDA’s drug and medical device approval process
- Most reported receiving only a basic or cursory level of teaching about FDA approvals and expressed a desire for additional education on these topics within their curriculum.
- Our study highlights an opportunity for curriculum revisions to increase teaching about FDA regulatory processes for drugs and medical devices across health professional schools.

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