Testimony Before the FDA's Psychopharmacologic Drugs and Drug Safety and Risk Management Advisory Committees

Immediate release oral amphetamine sulfate:

Properties *intended* to prevent *non-oral* abuse

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Testimony of Sidney Wolfe, MD
Health Research Group of Public Citizen

I have no financial conflicts of interest.

Increasingly minor role of ADF Opioid Prescriptions

● Abuse-deterrent formulations were introduced to the market in 2009. The utilization of ADF opioid formulations peaked in 2011, 5.6 million out of 258 million opioid prescriptions (2.2%), followed by a 51% decline by 2019 to 2.7 million out of 154 million prescriptions (1.8%).

● 10 years after ADF Oxycontin approval, there is no evidence that it resulted in “meaningfully reduced overall abuse.”

Significant 2015-2019 Decreases in Percentages of Opioid and Prescription Stimulant Misusers

Figure 25 Table. Past Year Opioid Misuse among People Aged 12 or Older: 2015-2019

Age	2015	2016	2017	2018	2019
12 or Older	4.7+	4.4+	4.2+	3.7	3.7
12 to 17	3.9+	3.6+	3.1+	2.8+	2.3
18 to 25	8.7+	7.3+	7.3+	5.6	5.3
26 or Older	4.2+	4.0+	3.8	3.6	3.6

+ Difference between this estimate and the 2019 estimate is statistically significant at the .05 level.

Figure 18 Table. Past Year Prescription Stimulant Misuse among People Aged 12 or Older: 2015-2019

Age	2015	2016	2017	2018	2019
12 or Older	2.0	2.1+	2.1+	1.9	1.8
12 to 17	2.0	1.7	1.8	1.5	1.7
18 to 25	7.3+	7.5+	7.4+	6.5	5.8
26 or Older	1.1	1.3	1.3	1.2	1.2

+ Difference between this estimate and the 2019 estimate is statistically significant at the .05 level.

Largest two-year decrease for any age group (18 to 25) in percentages of Opioid and Prescription Stimulant Misusers

	2017	2019	% decrease* 2017-2019
opioids	7.3 %	5.3%	27.4%
Rx stimulants	7.4%	5.8%	21.6%

*statistically significant

NSDUH data from 2019, Published September 2020

FDA Summary: AR19 lacks injection or intranasal deterrent effects

- In vitro manipulation studies demonstrated that it is feasible to obtain a solution for injection containing a reinforcing dose of amphetamine, under the conditions reported by the Applicant.

- The intranasal human abuse potential study does not provide convincing evidence that the formulation employed for AR19 has significant abuse-deterrent effects, as compared to amphetamine sulfate, when administered by the intranasal route.

FDA Slide PDF# 108

Considering the patterns of prescription stimulant nonmedical use in the United States, please discuss the potential public health impact of prescription stimulants formulated to be abuse-deterrent.

(FDA discussion question for of this meeting)

- The only way the committee could vote that the benefits outweigh the risks is to disregard FDA's conclusion that AR19 is not expected to reduce injection and intranasal abuse.
- The public health impact of a *purported* ADF version of amphetamine, with a predictable lowering of prescribing threshold because of some prescribers' belief in the ADF properties, would certainly lead to a negative impact on public health.
- The situation is painfully reminiscent of the Opana ER tragedy in which a reformulated version, eventually banned, was purported to have physicochemical properties expected to deter abuse by the intranasal and intravenous route. This new version was shown—too late---to have caused serious injection harms to public health, despite pre-approval in vitro evidence that "it can still be [redacted], cut [redacted] rendering it readily abusable by ingestion and intravenous injection, and possibly still by insufflation."

A Major Difference Between AR19 and Opana ER

- In the case of Opana ER, the scheduled fall 2011 advisory committee meeting to have reviewed its possible approval was irresponsibly cancelled because, as stated in the Opana ER approval package, there were “no unusual concerns regarding the efficacy or safety of this reformulated opioid.”

- Your committees have seen the evidence and will hopefully provide support for the analyses the FDA has provided.